

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO: ALL PLAINTIFFS LISTED IN EXHIBIT A TO PLAINTIFFS' MOTION	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**ETHICON'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS'
MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY
OF CHRISTINA PRAMUDJI, M.D.**

INTRODUCTION

Plaintiffs do not challenge Dr. Pramudji's expertise as a pelvic surgeon. *See, generally*, Plaintiffs' Motion to Exclude [Doc. No. 2035] and Memorandum in Support [Doc. No. 2037]. In fact, they do not discuss her qualifications at all or mention that she is a board-certified urologist with a sub-specialty in Pelvic Floor Medicine and Reconstructive Surgery. Prolapse Report at 7.¹ She has performed "well over 1000" prolapse surgeries and "over 900 sling procedures" to treat SUI. Prolapse Report at 7; TVT Report at 6. She has performed 10 to 20 complete explants and 50-60 revisions or partial removals. Ex. A, Pramudji (4/11/14) Dep. at 54.² She has also

¹ Dr. Pramudji submitted two reports in this case, one related to devices to treat pelvic organ prolapse (Gynemesh PS, Prosima and Prolift) (the "Prolapse Report," Exhibit B to Plaintiffs' Motion), and one related to devices to treat stress urinary incontinence (TVT and TVT-O) (the "TVT Report," Exhibit C to Plaintiffs' Motion), (collectively "Reports"). The general opinions set forth in these Reports and challenged here by Plaintiffs related to risks and warnings, design and efficacy and degradation are included in both Reports.

² While Plaintiffs relied upon this deposition from the *Huskey* matter, as well as Dr. Pramudji's March 23, 2016 and March 24, 2016 general depositions in this case, they attached cursory

taught surgeons across the country and at national conferences regarding the use of mesh devices and has consulted with medical device companies in the development of slings to treat SUI. Pramudji Prolapse Report at 7; TVT Report at 6. Plaintiffs do not discuss her reliance materials which include a large base of medical literature, including Level 1 evidence such as Cochrane Review meta-analyses assessing thousands of patients, and numerous randomized controlled trials (RCTs), not to mention public statements by medical societies in the fields of urology. Prolapse Report at 20-35; TVT Report at 24-27; 39-41; 44-51; 59-62; Reliance List, attached as Ex. B.³

Despite Dr. Pramudji's years of surgical experience and her review of considerable Level 1 peer-reviewed medical literature and RCTs, the Prolapse device IFUs, the TVT device IFUs and professional education materials, *see, e.g.*, Prolapse Report at 8-9; TVT Report at 7-8, Plaintiffs seek to preclude Dr. Pramudji from testifying about the adequacy of the device IFUs, arguing that she is not an expert on regulations governing device manufacturers and is instead relying solely on her experience as a surgeon. Plaintiffs' further seek to preclude her opinions, based upon her years of experience, that the devices are efficacious in design to treat pelvic organ prolapse or stress urinary incontinence and that the product benefits outweigh the product risks. Finally, Plaintiffs attempt again to preclude Dr. Pramudji from offering testimony that the polypropylene mesh products do not degrade in the human body. None of Plaintiffs' arguments has merit, and their Motion should be denied.

excerpts of her testimony as exhibits to their Motion. Given the nature of this Motion challenging her opinions, Ethicon attaches the full transcripts from each of these depositions in order for the Court to have a full record of Dr. Pramudji's education, training, experience and reliance materials, as well as a full understanding of her testimony in these matters.

³ While Plaintiffs attached Dr. Pramudji's Reports to their Motion, they did not include her reliance list, Ex. B to those Reports.

- **Product Warnings:** Dr. Pramudji's opinions related to the knowledge of pelvic floor surgeons who use these devices is based on her own education, her experience, her extensive review of the literature summarized in her Reports, and her reading of professional association statements. The legal standard is that Ethicon only has a duty to warn of risks unique to its devices and has no duty to warn of risks commonly known by pelvic floor surgeons. She is qualified to identify those risks.
- **Design.** Dr. Pramudji's design and risk-benefit opinions are based on her extensive experience in the use of these products, her clinical results and her examination of the medical literature, including studies assessing thousands of patients and randomized controlled trials. She is plainly qualified to testify on that subject and on the absence of literature to support Plaintiffs' alternatives.
- **Clinical Experience:** This Court has already previously rejected attempts to exclude practitioners, like Dr. Pramudji, from offering testimony regarding their own experiences with Ethicon's products related to the lack of degradation of the products.

ARGUMENT

I. Standard for admissibility of expert opinion testimony.

Ethicon incorporates by reference the standard of review for Daubert motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 U.S. Dist. LEXIS 92316, at *3-8 (S.D. W. Va. July 8, 2014).

II. Dr. Pramudji is qualified to address the adequacy of the IFUs and Ethicon's warnings based on her experience and supporting literature and studies.

Dr. Pramudji's opinions related to the IFUs and warning issues are housed not only in her personal education and clinical experience, but also in Level 1 evidence such as Cochrane Review meta-analyses assessing thousands of patients, and numerous randomized controlled trials (RCTs), not to mention public statements by medical societies in the fields of urology. Prolapse Report at 20-35; TVT Report at 24-27; 39-41; 44-51; 59-62; Reliance List, attached as Ex. B.

Plaintiffs' argument on this issue is that Dr. Pramudji did not rely upon FDA regulations or internal protocols at Ethicon concerning her opinion that the devices are not defective in

design. Plaintiffs' Memorandum at 4-5. This argument rests entirely on the supposition that expertise in FDA regulations related to requirements for IFUs is mandatory for these opinions.

Yet, the job of an expert witness is to provide the facts to which the court can apply the law. It is not the expert's job to provide the court with the law. This Court, in fact, has excluded testimony which not only stated facts but also expressed a legal conclusion. *In re Ethicon, Inc. Pelvic Repair Systems Product Liability Litigation (Lewis)*, 2014 WL 186872 (S.D. W. Va. 2014) at *20, citing *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). The important question here is whether Dr. Pramudji's testimony was consistent with the law to be applied to the case, and not whether she herself could articulate the governing legal standard. If she had attempted to do that, her testimony would have been excluded.

This Court's prior decision with regard to Dr. Pramudji's testimony on product warnings was concerned with testimony from an expert that, because she had not experienced certain risks in her clinical practice, then her opinion that such risks need not be contained in the IFU was improper. *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Memorandum Opinion and Order (*Daubert* Motions), Doc. 265 at 35 (S.D. W. Va. Nov. 20, 2014). That is not what Dr. Pramudji does here. Nor does she testify that, based upon the risks and complications she has seen in her clinical practice, "there are no other possible risks or complications that should have been included." *Mathison v. Boston Scientific Corp.*, 2015 WL 2124991, *27 (S.D. W. Va. May 6, 2015). Instead, her warning opinion and opinion that the IFUs are adequate is tied to the knowledge of pelvic floor surgeons based on their education and experience from performing pelvic surgery. Thus, the circumstances here are different from those in *Bellew*, and her opinions here are proper. See *Trevino v. Boston Scientific Corp.*, 2016 WL 1718836, *4 (S.D. W. Va.

April 28, 2016) (different circumstances may justify a different ruling when *Daubert* challenges are made).

The legal principle that controls here is that a device manufacturer’s duty to warn of adverse events is limited to events unique to the device. It does not include a duty to warn of risks commonly known to the surgeons who use the device. As stated generally in the RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY §2, cmt. j, a product seller “is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users.” *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§388(b), 402A, cmt. j; *Roney v. Gencorp*, 654 F. Supp. 2d 501 (S.D. W. Va. 2009) (adopting “sophisticated user” defense in §388).

This limitation on the duty to warn is recognized in medical cases as well. There is no duty to warn of risks that implanting surgeons commonly know. *See Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers “not well known to the medical community”). In fact, the FDA regulations recognize that information may be omitted from labeling “if, but only if, the article is a device for which directions, hazards, warnings and other information are *commonly known* to practitioners licensed by law to use the device.” 21 C.F.R. §801.109(c) (emphasis added).

The device IFUs restrict the class of surgeons who are to use the devices. They contemplate that users will be familiar with traditional surgical techniques used to treat stress urinary incontinence. *See, e.g.*, Ex. C, TVT IFU at 28 (“Users should be familiar with surgical techniques for bladder neck suspensions and should be adequately trained in implanting the TVT system before employing the TVT device.”); Ex. D, TVT-O IFU at 5 (“Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in the

Gynecare TVT Obturator procedure before employing the Gynecare TVT Obturator device.”); Ex. E, Prosima IFU at 12 (used only by physicians “familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes”). Pelvic surgeons know that these IFUs are not intended “to be comprehensive” because surgeons have a general base of knowledge about risks of surgery, and thus surgeons would not expect the IFU to be comprehensive. Ex. F, Pramudji (3/23/16) Prolapse Dep. at 110; 112.

So the important question with respect to Plaintiffs’ failure to warn claim is what “hazards” are “commonly known” to surgeons familiar with pelvic surgery, including surgery to address pelvic organ prolapse and SUI. Ethicon had no duty to warn of adverse events “commonly known” to those surgeons. Its duty was to warn of adverse events that were unique to the mesh devices. If Plaintiffs intend to argue at trial that Ethicon’s IFU failed to disclose certain risks, Ethicon is fully entitled to defend such claims by demonstrating that those risks were obvious to the users of the product (pelvic surgeons), and therefore, did not need to be included.

A. Dr. Pramudji’s experience as a urologist and pelvic surgeon renders her qualified to offer her opinions here regarding Ethicon’s warnings and IFUs.

Dr. Pramudji is well-qualified to testify to what pelvic surgeons know. She relies on her experience as a urologist with a sub-specialty in pelvic floor medicine and as a pelvic surgeon to discuss what risks of pelvic surgery would be known to such surgeons generally. She has taught other surgeons how to use such devices. She addressed that risks need not be included in the IFU or warnings unless they are clinically significant and that many risks of the use of mesh are also ordinary risks of performing any pelvic floor surgery. Ex. F, Pramudji (3/23/16) Prolapse Dep. at 120-22; Ex. G, Pramudji (3/24/16) Prolapse Dep. at 159-162; Ex. H, Pramudji (3/24/16) TVT Dep. at 38-44. Because of that, telling a surgeon of the risk is not necessary. Ex. F,

Pramudji (3/23/16) Prolapse Dep at 122; Ex. H, Pramudji (3/24/16) TVT Dep. at 47. This relates to adequacy of the IFU because the failure to warn analysis involves a determination of what the user of the product knew. Thus, a surgeon’s perspective on what pelvic surgeons know directly correlates with risks that do not need to be in the IFU. *See In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) (“[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings” (internal quotations and brackets omitted)).

This Court has permitted experts to opine about risks they perceive from surgery using mesh and whether those risks are covered by the applicable IFU. *See Huskey*, 29 F. Supp. 3d 691, 703, 719 (S.D. W. Va. 2014) (Drs. Rosenzweig and Blaivas adequately experienced physicians to testify to risks of surgery and whether the risks were addressed in the IFU despite lack of expertise in FDA regulations or standards governing device warnings); *Trevino v. Boston Scientific Corp.*, 2:13-cv-01617, 2016 WL 1718836, at *13-14 (S.D. W. Va. April 28, 2016) (Dr. Shull permitted to testify on adequacy of DFUs “from a clinician’s perspective”). Here, Dr. Pramudji relies on her experience as a pelvic surgeon to state that pelvic surgeons know certain risks are associated with pelvic surgery, with or without mesh augmentation, and thus their inclusion in the IFU would not be informing the user of the product.

Plaintiffs specifically asked Dr. Pramudji about lists of risks, including erosion, chronic pain syndrome, dyspareunia, the need for additional surgical intervention to address complications, the potential for life-changing complications, pelvic pain (Ex. F, Pramudji (3/23/16) Prolapse Dep. at 120-22); bleeding, hematoma, incontinence, urinary frequency, retention or obstruction, acute/chronic pain, wound dehiscence, nerve damage, recurrent

prolapse, foreign body response, pelvic pain, dyspareunia, contraction of tissue, damage to nearby organs, neuromuscular problems (Ex. G, Pramudji (3/24/16) Prolapse Dep. at 160); dyspareunia that may not resolve, difficulty in removing mesh if required, seroma, urge incontinence, adhesion formation, atypical vaginal discharge and death (Ex. H Pramudji (3/24/16) TVT Dep. at 38-43). As to each of these risks (except for erosion), Dr. Pramudji noted it was also a risk of any pelvic floor surgery, with mesh augmentation or without. *Id.* Dr. Pramudji testified that exposure or integration into tissues making removal difficult are also risks that can occur in surgeries without mesh because sutures can cause the same complications. Ex. H, Pramudji (3/24/16) TVT Dep. at 40-43.

Because of this, Dr. Pramudji could state objectively that any failure to include these particular risks in the IFU did not make the IFU inadequate since pelvic floor surgeons know these risks. *See* Ex. H, Pramudji (3/24/16) TVT Dep. at 47 (“pelvic surgeons are already familiar with all of these adverse reactions.”); Ex. G, Pramudji (3/24/16) Prolapse Dep. at 162 (“they are part of the body of knowledge of pelvic surgeons”); Ex. F, Pramudji (3/23/16) Prolapse Dep. at 122 (“I think those are risks that pelvic surgeons would anticipate, because as I stated, most of those risks, with the exception of the erosion, are risks of pelvic surgery.”). She further can testify that the lack of inclusion of such risks as adverse events would not “deprive a reader [surgeon] or mislead a reader [surgeon] of what the risks and benefits” of the devices were when the IFUs were published. *See, e.g., Huskey v. Ethicon, Inc.*, 29 F. Supp. 2d 691, 719 (S.D. W. Va. 2014) (addressing permissible scope of testimony from plaintiff’s expert urologist) (quoting *In re Diet Drugs Prods. Liab. Litig.*, 2000 WL 876900, at *11 (E.D. Pa. June 20, 2000)).

Plaintiffs’ assert that expert opinion based on experience without an explanation of how that experience leads to the conclusion reached is improper. Plaintiffs’ Response at 7. That did

not happen here. Dr. Pramudji was clear that literature and studies support her opinion, including Level 1 literature analyzing thousands of patients and RCTs, along with years of education and medical school training and her years of practice. Prolapse Report at 5, 19, 38, 47; TVT Report at 4-5, 15, 68-69. She therefore establishes a reliable basis for her opinions. This Court has recognized that experience in clinical practice is a proper basis for expert opinion. *Trevino*, at *14.

Contrary to Plaintiffs’ assertion, Dr. Pramudji’s opinions are not “based solely on her subjective belief and her status as an ‘expert’.” Plaintiffs’ Memorandum at 4. It is instead based on years of education, training, and clinical experience as well as a thorough review of medical studies and literature. She asserts that certain information is not necessary in the IFU because trained surgeons know the risk. And given that Ethicon’s IFUs direct that only pelvic floor surgeons trained in implantable materials should use the mesh products, the general knowledge of pelvic floor surgeons is wholly relevant to the inquiry of what should be in the IFU.

B. Dr. Pramudji’s opinions were never intended to rely on FDA regulations; nor do they need to in order to be admissible.

Dr. Pramudji is not offered to testify concerning the regulations applicable to product warnings or whether Ethicon complied with those regulations. Nor will she address internal Ethicon protocols related to product warnings or what risks Ethicon knew when the IFUs were drafted. Rather, Dr. Pramudji’s testimony is based on her perceptions as a pelvic surgeon, her knowledge of what risks a pelvic surgeon would know and medical literature and studies concerning risks.

Plaintiffs attempt to make much of the fact that Dr. Pramudji does not know if Ethicon warned of “all known risks,” yet this is not the standard under a failure to warn analysis. Plaintiffs’ Memorandum at 5. Nor is it the standard under the governing regulations related to

prescription medical devices. *See* 21 CFR § 801.109(c) (applicable to “Prescription devices”) (warning need not include “directions, hazards, warnings, and other information [] commonly known to practitioners licensed by law to use the device.”). This comports with the learned intermediary doctrine as well. Given that a manufacturer has no duty to warn of risks known or obvious to those using its product, the general knowledge of pelvic floor surgeons is the pinnacle inquiry. *See, e.g.*, Restatement (Third) of Torts: Product Liability §2 cmt. j (1998); Restatement (Second) of the Law of Torts §402A cmt. j; American Law of Product Liability 3d §32:69 (2016); *Willis v. Raymark Indus., Inc.*, 905 F.2d 793, 797 (4th Cir. 1990).

Plaintiffs selectively cite testimony out of context in support of the false notion that Ethicon’s employees supposedly admitted that all risks (regardless of whether obvious) must be disclosed in the IFU. Plaintiffs’ Memorandum at 6. Yet Dr. David Robinson testified that “that’s not true” and that physicians “shouldn’t depend on [the IFU] as the sole source of their information” regarding product risks. David Robinson, M.D., Dep. at 488:7- 9, 489:12-17 (Ex. G to Plaintiffs’ Motion [Doc. 2035]). As further noted by Dr. Charlotte Owens: “I would say that we listed the adverse reactions that we knew were adequate and sufficient for this document [the IFU]. . . . Physicians will not rely solely on the IFU for making their decisions . . . and ultimately will use their training, education, and experience, plus this document, to decide if they want to use it. . . . I don’t think you’re giving surgeons enough credit. Surgeons don’t have to figure out the complications of an area that they operate. Surgeons are trained to know the complications of the area in which they operate.” Charlotte Owens, M.D. Dep. at 310:10-13, 261:12-14, 262:2-5, 262:20-25 (Ex. F to Plaintiffs’ Motion [Doc. 2035]).

This supports Dr. Pramudji’s testimony that, while she did not review every email discussion or document ever created by Ethicon’s medical/regulatory affairs department, the

purpose of those departments is to consider everything that could possibly happen. Ex. F, Pramudji (3/23/16) Prolapse Dep. at 115 (Medical affairs is “going to have multiple discussions and opinions and bouncing things back and forth.”). Yet adequate warnings need not cover every potential or remote risk, particularly when the surgeon knows that such risks exist.

Nor does the fact that Dr. Pramudji does not know every step of the protocol within Ethicon to determine substantial risks defeat her testimony here. Dr. Pramudji is not offering the opinion that because she has not seen a risk, then it need not be in the warning. Rather, she is testifying that the litany of risks raised by Plaintiffs includes risks that are known to surgeons who perform pelvic surgeries. And most are the same risks whether mesh augmentation is used or not (except for erosion, which is listed in the IFUs).

Plaintiffs argue that Dr. Pramudji should be precluded from testifying about product warnings because she “has no knowledge of FDA requirements and no knowledge of industry standards.” Plaintiffs’ Memorandum at 4. As indicated above, while it is true that Dr. Pramudji does not have specialized knowledge about FDA regulations, Dr. Pramudji is competent to testify about how Ethicon’s IFUs would be perceived by pelvic surgeons. This Court has recognized that where an expert is not relying on the regulatory standards for warning opinions, addressing risks perceived in clinical practice and whether the warning conveys such risks are within an expert’s realm to make the comparison. *Trevino*, at *30. That is what Dr. Pramudji does here as it relates to the knowledge that pelvic surgeons have. She evaluated a host of risks that Plaintiffs urge should have been contained in the IFUs and, applying her clinical experience and education, determined whether those risks are ones that pelvic floor surgeons would have known, thus dispensing with the need for a specific warning in the IFU.

Since Dr. Pramudji is not offering testimony that the IFU was adequate for regulatory or FDA purposes, but instead opines that pelvic surgeons would have known that these risks exist just in performing pelvic surgery, then her opinion that the IFU was adequate when evaluating it from a surgeons' point of view is relevant and reliable.

III. Dr. Pramudji is Qualified to Opine on the Safety and Efficacy of the Devices and their Design as it Relates to Such.

Plaintiffs recognize early in their Memorandum that Dr. Pramudji's design opinions are related to safety and efficacy, i.e., the products as designed "have a positive benefit to risk profile." Plaintiffs' Memorandum at 3. For a surgeon using a medical device, the propriety of a product design is assessed in terms of the risks and benefits of the device, including the utility and the usefulness of the device as employed in the field. Her determination of lack of product defect is tied to the product's usefulness and safety not only in her hands, but as set forth in Level 1 evidence, randomized controlled trials and her review of systematic reviews and meta-analysis as well as Cochrane reviews. Pramudji Prolapse Report at 20-35; Pramudji TVT Report at 24-27; 39-41; 44-51; 59-62.

Nowhere does Dr. Pramudji suggest that she will discuss the design of the product in terms of Ethicon's protocols, FDA requirements or regulations, chemical content or polymer structures. Nor does her Report or testimony indicate that she intends to opine on failure modes effects analyses as related to product design. Plaintiffs' Memorandum at 9. And there is no requirement under *Daubert* that Dr. Pramudji review internal company design documents for her methodology to be reliable, as Plaintiffs argue, and this Court has never required as much. Although Plaintiffs rely on *Winebarger* to support their argument, that reliance is misplaced. Plaintiffs' Memorandum at 10. In that case, Dr. Shull sought to opine that the company had failed to follow its own internal protocols and that those protocols were lacking, even though he

had never seen any standard operating procedures for the company's medical device development or any of the internal design protocols. *Winebarger v. Boston Scientific Corp.*, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015). Dr. Shull's methodology was thus lacking "a necessary piece of data" and unreliable "regardless of the literature he has reviewed or the experience he has gained" because his methodology failed to include a review of the documents that would support his internal-protocols opinion. *Id.* By contrast, Dr. Pramudji here is not attempting to testify that Ethicon followed its own internal design protocols or that they were otherwise adequate. Accordingly, her opinion does not require a review of internal design protocols.

Nor does a defective design claim necessarily flow from such documents. Instead, whether a device is defective is assessed upon its safety, efficacy, usefulness, function, utility and desirability in the field in the hands of intended users, like Dr. Pramudji. Thus, Dr. Pramudji's opinions rely on her years of education and experience related to the pelvic floor anatomy and the use of mesh devices to treat prolapse and SUI, as well as on her clinical observations in performing hundreds of surgeries with such implantable devices, both implanting them and explanting them. Prolapse Report at 7; TVT Report at 6. In addition, Dr. Pramudji's opinions regarding the safety, efficacy, function, utility and desirability of the device in the field are based on her extensive review of the medical literature as set forth throughout her Reports. For example, in her TVT Report, she discusses the design of the TVT which is catalogued in the peer reviewed medical literature available to pelvic floor surgeons like herself. *See generally*, TVT Report at 22-27, citing Petros PE, Ulmsten UI., *An integral theory and its method for the diagnosis and management of female urinary incontinence*, Scand J Urol Nephrol Suppl. 1993; 153:1-93; Ulmsten U, et al., *An ambulatory surgical procedure under local anesthesia for*

treatment of female urinary incontinence, Int Urogynecol J Pelvic Floor Dysfunct. 1996; 7:81-5; Falconer C, et al., *Influence of different sling materials on connective tissue metabolism in stress urinary incontinent women*, Int Urogynecol J Pelvic Floor Dysfunct. 2001; 12 Suppl 2:S19-23. Similarly, in her Prolapse Report, she discusses the design of the Prolift device and in particular the medical literature supporting her opinions regarding design defect. *See generally*, Pramudji Prolapse Report at 17-21, citing Berrocal 2004.

Plaintiffs create a straw man regarding Dr. Pramudji's intended testimony on this topic by discussing certain Ethicon documents like design failure modes analysis, process failure modes analysis, and failure modes effects analysis. Plaintiffs' Memorandum at 9-12. Dr. Pramudji is not offering opinions on Ethicon's risk assessments or Ethicon's design protocols. Her design opinion is tied to her considerable clinical experience with the products and the risks and benefits of those products in that vast experience and as set forth in the extensive medical literature that she has reviewed as part of her assessment of the devices. She testified to such: "My opinions would go to how I feel the design is based on use in my hands and based on patient results. So I feel very confident and familiar with evaluating the design based on those parameters." Ex. G, Pramudji (3/24/16) Prolapse Dep at 186.

Dr. Pramudji has demonstrated that, as an experienced pelvic surgeon, she has expertise to testify as to whether the design of the devices was adequate to address the conditions for which they were being used, i.e., she can address the design in terms of the safety and efficacy of these devices. Ex. F, Pramudji (3/23/16) Prolapse Dep. at 63; Ex. G, Pramudji (3/24/16) Prolapse Dep. at 257-58; Ex. H, Pramudji (3/24/16) TVT Dep. at 67; Prolapse Report at 4-5; 34; 43; TVT Report at 7-8;15; 33. She is able to identify and explain that the design of products was effective in meeting the needs of her patients. Her opinions relate to the design *issue* as part of a

risk-utility analysis, but are not design opinions in the artificial sense set forth by Plaintiffs of a product design under certain Ethicon protocols or FDA requirements or regulations. Instead, she draws from her clinical experience and the relevant medical literature to determine that the product benefits outweigh the product risks and that it has utility and usefulness among other features. This Court has determined that such experience is sufficient for opinions of this nature. *See Trevino*, at *6.

Given her experience, and the opposing opinions of Plaintiffs' experts that are also based on their experience, it is reliable and relevant for her to testify that in her hundreds of uses of these products, the design was efficacious in treating difficult pelvic floor disorders. Pramudji TVT Report at 69; Pramudji Prolapse Report at 6.

Plaintiffs argue that Dr. Pramudji's opinions on risks and benefits should be excluded because she cannot cite to specific complication rates. Plaintiffs' Memorandum at 13-14. However, any claimed lack of support (which Ethicon disputes), is not required. *Winebarger*, 2015 WL 1887222, at *34 (expert's inability to provide "exact statistics" about the outcome of his patients did not render his personal experience opinions unreliable as "such detail is not required under *Daubert* to opine as to 'large-scale safety and efficacy of the [] device.'"). Any asserted failure in her analysis is better addressed on cross examination than by excluding the testimony. *Trevino*, at *23. This is especially true where Dr. Pramudji relies extensively on high level and scientifically reliable medical studies and literature to support her conclusions as set forth in her Reports, and not simply on rough calculations discussed during her deposition. *See* Ex. G, Pramudji (3/24/16) Dep. at 239.

IV. Dr. Pramudji's Degradation Opinions are Well-Supported and Proper.

Dr. Pramudji has performed 10 to 20 complete explants and 50-60 revisions or partial removals. Ex. A, Pramudji (4/11/14) Dep. at 54. She looked at the material she explanted and found no degradation. Ex. A, Pramudji (4/11/14) Dep. at 140. She has looked at pictures of polypropylene under a microscope and has reviewed images of explanted material provided to her by pathologists. Ex. A, Pramudji (4/11/14) Dep. at 139-140. In her review of 10-20 slides of explanted mesh, she found no evidence of degradation. Ex. A, Pramudji (4/11/14) Dep. at 140.

This Court has previously permitted Dr. Pramudji to testify regarding her personal clinical experience related to the lack of degradation of pelvic mesh products. *Huskey*, 29 F. Supp. 3d 691, 727 (S.D. W. Va. 2014); *Bellew*, Memorandum Opinion and Order (*Daubert* Motions), at 33. This Court recently reiterated its conclusion that an expert's reliance on scientific articles combined with clinical experience constitutes reliable, scientific methodology to offer an opinion concerning degradation of polypropylene mesh. *Trevino*, at *14-15; *106. Dr. Pramudji seeks to do the same here.

Recognizing that this Court has permitted such opinions in *Huskey*, Plaintiffs claim that Dr. Pramudji's opinions here go beyond what this Court allowed there. Plaintiffs' Memorandum at 15. Yet, Plaintiffs rely solely on Dr. Pramudji's testimony from the *Huskey* case in support of their motion to exclude her allegedly broader-than-*Huskey* degradation opinions. Plaintiffs' Memorandum at 15-17. The opinions on degradation that they attack here are the *very same ones* challenged in *Huskey* that this Court allowed.

Dr. Pramudji is qualified by education, training and experience to offer the opinion that polypropylene mesh does not degrade. Plaintiffs again build a straw man to try to preclude this testimony by arguing that Dr. Pramudji does not know the "scientific, chemical or structural make-up" of polypropylene. Plaintiffs' Memorandum at 15-16. Such specific information is not

needed in order to discuss the fact that she has seen no degradation in her clinical practice and that the literature and studies do not support Plaintiffs' theory.

Dr. Pramudji's opinion is further supported by the literature and studies she cited that support her position. Pramudji Prolapse Report at 35-36; Pramudji TVT Report at 62-65. She testified that she relied upon dozens of articles and studies in formulating this opinion, along with her personal experience as a urologist and surgeon. Ex. A, Pramudji (4/11/14) Dep. at 39-40. She is "always reviewing the literature, looking for all the information that I can regarding the sling and mesh cases." Ex. A, Pramudji (4/11/14) Dep. at 39. She testified that the literature does not support degradation and that studies show that in millions of women, polypropylene mesh has not been shown to degrade. Ex. A, Pramudji (4/11/14) Dep. at 146, 148.

According to Dr. Pramudji, the "literature definitely supports it [no degradation] when we don't see problems that can be related back to degradation in the literature." Ex. F, Pramudji (3/23/16) Prolapse Dep. at 71. In the studies she cites, "where they remove the mesh, the mesh is there. You know, it's not -- it doesn't disappear. It doesn't degrade over time. I mean, if Prolene degraded, they would not use it in cardiac surgery to rely on sewing together arteries." *Id.* at 76. And this is supported in her personal experience removing mesh, "it's not like you see it disintegrating. It's not falling apart in front of your eyes." *Id.*

Plaintiffs challenge Dr. Pramudji's literature and studies, arguing that because remote studies exist that are purportedly contrary to her opinions, then her opinions must be excluded. Plaintiffs' Motion at 16-17. Dr. Pramudji admits such remote studies exist. She just finds them unpersuasive in light of the vast high-level information and literature to the contrary. Ex. F, Pramudji (3/23/16) Prolapse Dep. at 76-77. Further, the existence of claimed contrary studies is fodder for cross examination, not a basis to exclude Dr. Pramudji's opinions as unreliable when

they are based both on her considerable personal experience as well as medical literature and studies. *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) (“the court need not determine that the expert testimony a litigant seeks to offer into evidence is irrefutable or certainly correct.”).

As to Plaintiffs’ argument that Dr. Pramudji did not personally conduct tests or look at polypropylene under a microscope, such personal testing is not a prerequisite to admissibility, as this Court found in *Huskey*. See Plaintiffs’ Memorandum at 16. Here, Dr. Pramudji’s opinions are the result of her extensive education, training, experience and appropriate reliance upon applicable medical literature. These opinions need not be accompanied by her personal testing.

Plaintiffs’ argument for exclusion also relies upon Dr. Pramudji’s alleged lack of practical experience applying her chemical engineering degree; lack of work in the general field of chemical engineering; lack of specialized education or training related to polypropylene; and lack of education or training on the structural make-up of Ethicon medical devices or components. Plaintiffs’ Memorandum at 15-16. All of this overlooks the fact that Dr. Pramudji is a board-certified urologist who specializes in pelvic floor disorders and who has performed hundreds of surgeries utilizing these mesh devices and has reviewed the medical literature, including the unreliable literature that Plaintiffs’ experts rely upon. She has been permitted in the past to testify to the lack of evidence of degradation in her clinical practice. She testifies to the vast body of medical literature that supports her. To the extent that Plaintiffs disagree with her conclusion, then cross examination, and not exclusion, is the appropriate vehicle to address that.

CONCLUSION

For the reasons set forth above, the Court should deny Plaintiffs' Motion to Exclude Certain Opinions of Christina Pramudji, M.D.

Respectfully submitted,

ETHICON, INC. AND
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CERTIFICATE OF SERVICE

I certify that on May 9, 2016, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones

Christy D. Jones

Christina Pramudji, M.D.

<p style="text-align: right;">Page 1</p> <p>1 IN THE UNITED STATES DISTRICT COURT 2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA 3 CHARLESTON DIVISION 4 IN RE: ETHICON, INC., 5 PELVIC REPAIR SYSTEMS 6 PRODUCTS LIABILITY LITIGATION MDL NO. 2327</p> <hr/> <p>7 Jo Huskey and Allen 8 Huskey, 9 Plaintiffs, 10 v. Case No. 2:12-cv-05201 11 Ethicon, Inc., et al., 12 Defendants.</p> <p>13 14 ORAL DEPOSITION OF 15 CHRISTINA PRAMUDJI, M.D. 16 Friday, April 11, 2014</p> <p>17 18 19 20 21 22 GOLKOW TECHNOLOGIES, INC. 23 877.370.3377 ph 917.591.5672 fax 24 deps@golkow.com</p>	<p style="text-align: right;">Page 2</p> <p>1 ORAL DEPOSITION OF CHRISTINA 2 PRAMUDJI, M.D., produced as a witness at the 3 instance of the Plaintiffs, and duly sworn, 4 was taken in the above styled and numbered 5 cause on Friday, April 11, 2014, from 6 10:06 a.m. to 4:18 p.m., before Susan Perry 7 Miller, CSR-TX, CCR-LA, CSR-CA, CLR, CRR, 8 RDR, Notary Public in and for the State of 9 Texas, reported via Machine Shorthand with 10 Realtime Computer Translation and Interactive 11 Realtime Technology, at the Westin Memorial 12 City, 945 Gessner Road, Houston, Texas 13 pursuant to the Federal Rules of Civil 14 Procedure. 15 --oOo-- 16 17 18 19 20 21 22 23 24</p>
<p style="text-align: right;">Page 3</p> <p>1 APPEARANCES 2 3 FOR PLAINTIFFS: 4 MOTLEY RICE LLC 5 321 South Main Street, 2nd Floor 6 Providence, Rhode Island 02903 7 (T) 401.457.7700 (F) 401.457.7708 8 By: Fidelma Fitzpatrick, Esq. 9 ffitzpatrick@motleyrice.com 10 11 WEXLER WALLACE LLP 12 55 West Monroe Street, Suite 3300 13 Chicago, Illinois 60603 14 (T) 312.346.2222 (F) 312.346.0022 15 By: Edward A. Wallace, Esq. 16 eaw@wexlerwallace.com 17 18 LAW OFFICE OF MARGARET M. THOMPSON 19 101 Colorado Street, No. 3304 20 Austin, Texas 78701 21 (T) 512.695.1708 22 By: Margaret M. Thompson, M.D., J.D. 23 mthompsonmd@gmail.com 24</p>	<p style="text-align: right;">Page 4</p> <p>1 APPEARANCES, Continued: 2 3 FOR DEFENDANTS: 4 BUTLER SNOW LLP 5 500 Office Center Drive, Suite 400 6 Fort Washington, Pennsylvania 19034 7 (T) 267.513.1885 (F) 267.513.1701 8 By: Nils B. (Burt) Snell, Esq. 9 burt.snell@butlersnow.com 10 11 12 --oOo-- 13 14 15 16 17 18 19 20 21 22 23 24</p>

1 (Pages 1 to 4)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 5</p> <p>1 INDEX</p> <p>2 ORAL DEPOSITION OF</p> <p>3 CHRISTINA PRAMUDJI, M.D., APRIL 11, 2014</p> <p>4 Page</p> <p>5 APPEARANCES 3</p> <p>6 PRELIMINARY PROCEEDINGS 7</p> <p>7</p> <p>8 EXAMINATION OF CHRISTINA PRAMUDJI, M.D.:</p> <p>9 BY MS. KIRKPATRICK..... 7</p> <p>10 BY MR. SNELL.....253</p> <p>11 BY MS. KIRKPATRICK.....264</p> <p>12 BY MR. SNELL.....267</p> <p>13</p> <p>14 CERTIFICATE 268</p> <p>15 LAWYER'S NOTES 269</p> <p>16</p> <p>17</p> <p>18</p> <p>19 Deposition Support Index:</p> <p>20 Page / Line</p> <p>21 Instruction Not to Answer 45 12</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 6</p> <p>1 EXHIBIT INDEX</p> <p>2 Description Page</p> <p>3 Pramudji-1 Notice of Deposition 9</p> <p>4 and Document Requests</p> <p>5 Pramudji-2 Expert Report of 9</p> <p>6 Christina Pramudji, M.D.</p> <p>7 Report of IME on 10</p> <p>8 Jo Huskey</p> <p>9 Pramudji-4 "Sling surgery for 29</p> <p>10 stress urinary</p> <p>11 incontinence in women:</p> <p>12 a systematic review and</p> <p>13 metaanalysis"</p> <p>14 Pramudji-5 "Randomized Trial of 29</p> <p>15 Tension-Free Vaginal</p> <p>16 Tape and Tension-Free</p> <p>17 Vaginal Tape-Obturator</p> <p>18 for Urodynamic Stress</p> <p>19 Incontinence in Women"</p> <p>20 Pramudji-6 "Polypropylene mesh: 30</p> <p>21 evidence for lack of</p> <p>22 carcinogenicity"</p> <p>23 Pramudji-7 "Long-Term Results of 32</p> <p>24 Burch Colposuspension"</p> <p>25 Pramudji-8 "Five-year Results of a 32</p> <p>Randomized Trial</p> <p>Comparing Retropubic</p> <p>and Transobturator</p> <p>Midurethral Slings for</p> <p>Stress Incontinence"</p> <p>Pramudji-9 Gynecare TVT Obturator 149</p> <p>System Instructions for</p> <p>Use</p> <p>Pramudji-10 Pelvic Illustration 166</p> <p>with Handwritten Labels</p> <p>--oOo--</p>
<p style="text-align: right;">Page 7</p> <p>1 PRELIMINARY PROCEEDINGS</p> <p>2 (Friday, April 11, 2014, 10:06 a.m.)</p> <p>3 (Witness sworn by the reporter.)</p> <p>4 PROCEEDINGS</p> <p>5 CHRISTINA PRAMUDJI, M.D.,</p> <p>6 having taken an oath to tell the truth, the</p> <p>7 whole truth, and nothing but the truth, was</p> <p>8 examined and testified as follows:</p> <p>9 EXAMINATION</p> <p>10 BY MS. KIRKPATRICK:</p> <p>11 Q. Good morning, Dr. Pramudji. Can</p> <p>12 you state your name and your address for the</p> <p>13 record, please?</p> <p>14 A. Christina Pramudji, M.D.,</p> <p>15 2 Lorriellake Lane, Houston, Texas 77024.</p> <p>16 Q. And where are you currently</p> <p>17 employed?</p> <p>18 A. Texas Oncology, Texas Urology</p> <p>19 Specialists.</p> <p>20 Q. Okay. And is that here in</p> <p>21 Houston?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. Now, Dr. Pramudji, you've</p> <p>24 been deposed before, correct?</p>	<p style="text-align: right;">Page 8</p> <p>1 A. Yes.</p> <p>2 Q. And how many times have you been</p> <p>3 deposed?</p> <p>4 A. In this particular litigation or</p> <p>5 mesh litigation, twice.</p> <p>6 Q. Okay.</p> <p>7 A. With Schubert --</p> <p>8 Q. Do you remember what case?</p> <p>9 A. The Schubert case and the Lewis</p> <p>10 case.</p> <p>11 Q. And do you know where the</p> <p>12 Schubert case was based or out of, what</p> <p>13 state?</p> <p>14 A. Missouri.</p> <p>15 Q. And the Lewis case?</p> <p>16 A. It was an MDL case.</p> <p>17 Q. And you understand that you're</p> <p>18 here today in connection with a case that is</p> <p>19 in the MDL, correct?</p> <p>20 A. Yes.</p> <p>21 Q. And it's against Ethicon.</p> <p>22 A. Yes.</p> <p>23 Q. Okay. During the course of the</p> <p>24 day, I'm going to be asking you a series of</p>

2 (Pages 5 to 8)

Page 9

1 questions. If you can't hear me or you don't
2 understand what I'm asking, please just let
3 me know and I'm happy to rephrase it. If you
4 do go ahead and answer, I'll just assume that
5 you understood what it was that I was looking
6 for.

7 If you need to take a break,
8 stretch your legs, use the ladies' room,
9 please, just let me know. This is not an
10 endurance test so if you need a little bit of
11 a break, that's not an issue at all.

12 Before we get started today, I'm
13 going to mark a couple of exhibits.
14 (Whereupon, Exhibit Pramudji-1,
15 Notice of Deposition and Document
16 Requests, was marked for identification.)

17 BY MS. KIRKPATRICK:

18 Q. Marked as Exhibit 1 is the notice
19 of deposition, and let me show that to you.
20 Have you seen that document before?

21 A. Yes.

22 Q. Okay.

23 (Whereupon, Exhibit Pramudji-2,
24 Expert Report of Christina Pramudji,

Page 11

1 MR. SNELL: For the record, there
2 were urodynamics that were also sent
3 over.

4 MS. KIRKPATRICK: Yes, we're
5 going to be marking those later. Thank
6 you.

7 BY MS. KIRKPATRICK:

8 Q. Okay. You just testified that
9 you gave testimony previously in the Lewis
10 case in the MDL. Is that right?

11 A. That's correct.

12 Q. And what kind of device did
13 Ms. Lewis have?

14 A. She had a retropubic TDT.

15 Q. And you also testified that you
16 had been deposed in the Schubert case in
17 Missouri. What kind of device did
18 Ms. Schubert have?

19 A. She had a Prolift.

20 Q. And in the Lewis case you gave
21 deposition testimony. Is that correct?

22 A. Yes.

23 Q. But you did not testify at trial
24 in that matter?

Page 10

1 M.D., was marked for identification.)

2 BY MS. KIRKPATRICK:

3 Q. And I'm going to show now what's
4 been marked as Deposition Exhibit 2. Can you
5 identify that for me?

6 A. That's my expert report in
7 relation to this case.

8 Q. Okay. You want to take a quick
9 look through and make sure that, at least at
10 a quick glance, that that's a complete copy?
11 (Witness reviews document(s).)

12 A. Yes, it is.

13 (Whereupon, Exhibit Pramudji-3,
14 Report of IME on Jo Huskey, was marked
15 for identification.)

16 BY MS. KIRKPATRICK:

17 Q. Okay. And then I'm going to show
18 you what's been marked as Deposition
19 Exhibit 3 and ask you what that is.

20 A. That is the report of my IME for
21 Mrs. Huskey.

22 Q. Okay. We'll be marking some more
23 exhibits throughout the day, but these are
24 ones that we will refer to often.

Page 12

1 A. That's correct.

2 Q. Have you ever testified at trial
3 in any mesh-related cases?

4 A. Not as of yet.

5 Q. Okay. And it's my understanding
6 from having reviewed your deposition in the
7 Lewis case that you set forth a number of
8 general opinions concerning Ethicon and
9 concerning the TVT line of products. Is that
10 right?

11 A. Yes.

12 Q. Do you recall those opinions in
13 this case as well?

14 A. Yes.

15 Q. What I'd like to do is, I don't
16 want to have to go through and redepose you
17 on the same things that you've been deposed
18 before, so let me ask you this way: Is there
19 anything that you testified to in the Lewis
20 deposition concerning Ethicon or concerning
21 TVT, the substance of these issues, that you
22 wish to change or amend or alter at any
23 point?

24 A. No.

Page 13

1 Q. Okay. So the opinions that you
2 espoused in that particular deposition remain
3 current today?

4 A. Yes.

5 Q. And you've incorporated them into
6 your opinions in Ms. Huskey's case as well?

7 A. Correct.

8 Q. Okay. In addition to your
9 mesh-related depositions, have you given
10 depositions in any other kind of case?

11 A. Yes, I have.

12 Q. Okay. And what are those?

13 A. When I was in residency, I was
14 deposed as a resident who placed an
15 endotracheal tube on a patient as a fact
16 witness.

17 Q. Uh-huh. And that was not expert
18 testimony?

19 A. No.

20 Q. And were you a defendant in that
21 lawsuit?

22 A. No.

23 Q. Was it a medical malpractice
24 lawsuit?

Page 14

1 A. Yes.

2 Q. Okay. Any other testimony that
3 you've given?

4 A. Yes.

5 Q. Okay. And what's that?

6 A. I was a defendant in a lawsuit
7 in -- approximately 10 years ago, a patient
8 of my partner's who expired unexpectedly, and
9 I was the physician on call; and that case
10 was dropped against -- against me and against
11 my partner.

12 Q. Okay.

13 A. And they only sued the hospital.

14 Q. Okay. And what was -- was the
15 patient an inpatient at the time?

16 A. Yes.

17 Q. And what was the condition that
18 he or she --

19 A. He was in the hospital for a
20 kidney stone and subsequently was found to
21 have a renal mass as well.

22 Q. Okay. And did you give your
23 testimony in that case?

24 A. I was deposed.

Page 15

1 Q. You were deposed.

2 A. Yes.

3 Q. Okay. And that was as a
4 defendant?

5 A. As a defendant.

6 Q. Okay. Any other cases?

7 A. And there was one other case
8 where my group was the defendant, and I was
9 the representative of the group in a patient
10 that was in the hospital with gross hematuria
11 and had a bladder rupture.

12 Q. Okay.

13 A. And that case was dropped against
14 the group.

15 Q. And you gave deposition testimony
16 there?

17 A. Yes, I did.

18 Q. Okay. Any other cases where you
19 or your practice was a defendant to a
20 lawsuit?

21 A. No.

22 Q. Okay. Any other cases in which
23 you gave a deposition?

24 A. No.

Page 16

1 Q. Are these mesh cases that you're
2 testifying on behalf of Ethicon, are those
3 the first cases where you've served as an
4 expert witness?

5 A. Yes.

6 Oh, I'm sorry, no. There is
7 another case where I served as an expert
8 witness for a drugstore company. It was a
9 patient -- yeah, I guess a person, a customer
10 of theirs, who fell in their store and
11 claimed that the fall caused urinary
12 incontinence; and I was not deposed. I just
13 wrote an expert report or expert opinion.

14 Q. On behalf of the drugstore?

15 A. Correct.

16 Q. And your opinion in that case --

17 A. Was that the fall did not cause
18 the incontinence. She had that before the
19 fall.

20 Q. Okay. Is there anything else?

21 A. That's all.

22 Q. Okay. So you understand that in
23 Ms. Huskey's case, you're serving as an
24 expert witness for Ethicon. Is that right?

<p style="text-align: right;">Page 17</p> <p>1 A. Yes.</p> <p>2 Q. But in addition to serving as an</p> <p>3 expert in the litigation and the -- let me</p> <p>4 make sure I get this right -- Schubert, Lewis</p> <p>5 and Huskey cases, you've also done other work</p> <p>6 for Ethicon. Isn't that right?</p> <p>7 A. That's correct.</p> <p>8 Q. Okay. So can you tell me what it</p> <p>9 is, what type of work you have done for</p> <p>10 Ethicon outside of the expert witness arena?</p> <p>11 A. Sure. I have done primarily</p> <p>12 preceptorship work, teaching other physicians</p> <p>13 the techniques with Prolift, TVT-O, Solyx --</p> <p>14 not Solyx -- TVT-Secur and Prolift+M. I have</p> <p>15 done some advisory panels, for which I was</p> <p>16 reimbursed. And I have helped moderate at</p> <p>17 meetings and at their booth at the AUA.</p> <p>18 Q. And in each of these positions,</p> <p>19 you were compensated for the work that you</p> <p>20 did for Ethicon?</p> <p>21 A. Yes, I was.</p> <p>22 Q. And how much -- were you</p> <p>23 compensated on an hourly basis?</p> <p>24 A. They typically do it as a</p>	<p style="text-align: right;">Page 18</p> <p>1 half-day basis.</p> <p>2 Q. Okay. And how much were you</p> <p>3 reimbursed for a half day?</p> <p>4 A. \$1,500.</p> <p>5 Q. Okay. And how much are you</p> <p>6 compensated in this litigation for the work</p> <p>7 that you do for Ethicon?</p> <p>8 A. \$600 per hour or \$700 per hour</p> <p>9 for deposition and trial.</p> <p>10 Q. Okay. When did you begin doing</p> <p>11 work for Ethicon?</p> <p>12 A. Around 2005.</p> <p>13 Q. And how did you come to work with</p> <p>14 Ethicon regarding their mesh products?</p> <p>15 A. My senior partner, Dr. Anhalt,</p> <p>16 had been a preceptor for Ethicon for the TVT</p> <p>17 retropubic. He was the first person in</p> <p>18 Houston to do that procedure, and so he had a</p> <p>19 relationship with Ethicon. And we operate</p> <p>20 together quite a bit so he recommended to</p> <p>21 them that they start to involve me as well,</p> <p>22 and we would do the preceptorships together.</p> <p>23 Q. Okay.</p> <p>24 A. Most of the advisory boards and</p>
<p style="text-align: right;">Page 19</p> <p>1 the preceptorships, we would do together.</p> <p>2 Q. And does that continue to this</p> <p>3 day, that you do most of that work with your</p> <p>4 partner?</p> <p>5 MR. SNELL: Form.</p> <p>6 A. No. We don't have -- we don't do</p> <p>7 preceptorships anymore.</p> <p>8 BY MS. KIRKPATRICK:</p> <p>9 Q. You don't do them at all?</p> <p>10 A. No. They haven't had any new</p> <p>11 products that they need preceptors for.</p> <p>12 Q. Okay. So I want to just go</p> <p>13 through a list of work you may have done with</p> <p>14 Ethicon and just establish some basic facts</p> <p>15 about it. You testified that you've been</p> <p>16 parts of advisory boards or advisory panels?</p> <p>17 Is that right?</p> <p>18 A. Yes.</p> <p>19 Q. And was that compensated at that</p> <p>20 rate of \$1500 a half day?</p> <p>21 A. Yes.</p> <p>22 Q. What advisory boards or panels</p> <p>23 did you work on for Ethicon?</p> <p>24 A. I can only remember a couple off</p>	<p style="text-align: right;">Page 20</p> <p>1 the top of my head. There was one where they</p> <p>2 wanted to hear from urologists, it was</p> <p>3 specifically urologists that went to their</p> <p>4 headquarters in New Jersey, and they were</p> <p>5 getting our feedback on the mesh procedures</p> <p>6 and future directions that they might want to</p> <p>7 take.</p> <p>8 Q. Uh-huh.</p> <p>9 A. And I remember one that was</p> <p>10 specifically just Dr. Anhalt and I and they</p> <p>11 had some sort of secret new procedures that</p> <p>12 they were kind of just throwing -- you know,</p> <p>13 getting our feedback on, getting our opinion</p> <p>14 on.</p> <p>15 Q. Okay. Do you remember any</p> <p>16 others?</p> <p>17 A. I can't remember any others off</p> <p>18 the top of my head.</p> <p>19 Q. Okay. Do you remember just</p> <p>20 generally how many advisory boards you'd have</p> <p>21 served on for Ethicon, the ballpark figure?</p> <p>22 A. I feel like there may have been</p> <p>23 one or two more than what I can remember.</p> <p>24 Q. Okay. So it's safe to say</p>

Christina Pramudji, M.D.

Page 21

1 somewhere between maybe two and five?

2 A. Yes.

3 Q. Okay. You also testified that
4 you were a sponsored speaker or somebody
5 who's addressed or spoken on behalf of
6 Ethicon at meetings? Is that right?

7 A. Yes.

8 Q. Okay. And can you tell me which
9 meetings you spoke about -- or, excuse me,
10 strike that.

11 Can you tell me which meetings
12 you represented Ethicon at?

13 MR. SNELL: Form. Go ahead.

14 A. AUA in Anaheim; that would have
15 been around -- let's see -- 2007, I believe.
16 I helped give some talks about cases at the
17 AUA booth.

18 BY MS. KIRKPATRICK:

19 Q. Uh-huh.

20 A. And then at one of the last -- I
21 think the last TVT summit, which was in
22 Sonoma, I moderated a -- what did they call
23 it -- it was sort of a case discussion where
24 one physician would present cases and I would

Page 22

1 moderate the questions and, you know, if
2 people wanted to ask questions and bring up
3 certain issues that we would talk about.

4 Q. Did these involve SUI products,
5 POP products or both?

6 A. Both.

7 Q. Okay. So you gave me two that
8 you remember. Are there any others? Can you
9 give me a ballpark of how many times you
10 served as a compensated speaker for --

11 A. That's all I can remember for
12 that.

13 Q. Okay. You also said that you did
14 preceptorship work on Prolift, Prolift Plus
15 and TVT-O, TVT Secur. Is that right?

16 A. Yes.

17 Q. Have you ever done it for the
18 TVT Classic?

19 A. No.

20 Q. How many times have you done
21 preceptorships for the TVT-O?

22 A. It would have been in conjunction
23 with the Prolift cases. They would not have
24 been separate preceptorships only for that.

Page 23

1 Q. Okay. And do you know about how
2 many times?

3 A. Maybe somewhere between five and
4 10, I would say.

5 Q. Okay. Have you ever presented to
6 the sales force or any sales representatives
7 at Ethicon?

8 A. No.

9 Q. Have you ever performed any
10 product research for Ethicon?

11 A. No.

12 Q. Have you ever received any grant
13 money from Ethicon to perform research or do
14 any kind of medical reviews for them?

15 A. No.

16 Q. Have you ever been asked to
17 provide any information or input into
18 publications that Ethicon is doing?

19 A. No.

20 Q. Have you ever participated in any
21 design validation projects?

22 A. No.

23 Q. So in other -- in addition to the
24 things that we've spoken about, is there

Page 24

1 anything else that you have done for Ethicon
2 outside of the expert arena between 2005,
3 when you started working with them, through
4 the present?

5 A. Not that I can recall.

6 Q. Can you tell me how much money to
7 date you have been paid by Ethicon for your
8 non-expert work?

9 A. I don't remember that number.
10 That was presented in the prior case, so that
11 data is available.

12 Q. Okay. Since that time, have you
13 been compensated by Ethicon for any
14 non-expert work?

15 A. No.

16 Q. So the numbers that you gave in
17 the Lewis case would be current through
18 today?

19 A. That's correct.

20 Q. Okay. When did you become
21 retained or when did Ethicon retain you to
22 work as an expert in pelvic mesh litigation?

23 A. They started talking to me about
24 a year and a half ago, is the initial

6 (Pages 21 to 24)

Christina Pramudji, M.D.

Page 25

1 meeting, and then I officially was retained
2 last summer, 2013.

3 Q. So retained in the summer of
4 2013.

5 And who approached you about
6 working with Ethicon as an expert?

7 A. The first person was Michael
8 Brown.

9 Q. And who else have you spoken to
10 concerning your work with -- as an expert
11 witness for Ethicon?

12 MR. SNELL: In any -- just so I
13 understand, in any kind of shape, form?
14 Depositions, trial?

15 MS. KIRKPATRICK: Yeah, just who
16 have you spoken to.

17 MR. SNELL: Okay.

18 A. Well, of course, Burt Snell,
19 Christy Brown -- I mean Christy Jones. Where
20 did that come from? Christy Jones.

21 BY MS. KIRKPATRICK:

22 Q. Don't tell her that, okay?

23 A. I'm sorry.

24 And when I was in Charleston,

Page 26

1 West Virginia, I met several attorneys but I
2 don't remember all their names.

3 Q. Okay. But you've primarily
4 worked with Mr. Snell and Ms. Jones on these
5 cases. Is that right?

6 A. Yes. Oh, I did do one deposition
7 prep with Anita Modak-Truran.

8 MR. SNELL: Good enough.

9 BY MS. KIRKPATRICK:

10 Q. Okay. Anyone else?

11 A. No, that's all.

12 Q. Okay. And can you tell me, were
13 the figures that you relayed before in your
14 Lewis testimony current as of that time on
15 the amount of money that you've been paid for
16 expert services by Ethicon?

17 A. Yes.

18 Q. Okay. Since the time of your
19 Lewis deposition, how much money have you
20 been paid by Ethicon for your expert
21 services?

22 A. I would have to look at the exact
23 number. I can give you a ballpark. It was
24 around \$50,000.

Page 27

1 Q. Okay. So your best estimate,
2 sitting here, is that you've been paid
3 another \$50,000?

4 A. Correct.

5 Q. Is there any amount that you've
6 billed that's still owing to date?

7 A. No.

8 Q. You've billed for all of your
9 services, except, I'm assuming, for the
10 deposition here today, and you've been
11 compensated for everything that you have
12 done?

13 A. No. I haven't billed for my
14 Huskey -- anything related to Huskey as of
15 yet.

16 Q. Okay. How much time have you
17 spent on Ms. Huskey's case, approximately?

18 A. Specifically on Ms. Huskey's
19 case, about 50 hours.

20 Q. Can you tell me what you did in
21 that 50 hours, just a general breakdown of
22 the type of work that you did?

23 A. Yeah. I reviewed the medical
24 records, the depositions, write the report;

Page 28

1 the IME, writing the report for that.
2 Reviewing the literature, preparing for
3 today.

4 Q. Okay. Let me just ask you
5 briefly about the literature. In your
6 previous testimony in Lewis and in the expert
7 report that you gave there, you had opinions
8 about what the literature reflected
9 concerning TVT devices.

10 A. Uh-huh.

11 Q. Is there any other literature
12 that you are relying on in this case in
13 addition to what you discussed or what you
14 identified in the Lewis case?

15 A. Yes. There are a couple of
16 papers that have -- that I've added.

17 Q. Okay. Can you tell me which
18 those are?

19 A. I'd have to go through it and
20 look.

21 Q. Yeah, whatever you need to look
22 at is fine.

23 A. And I may -- there may be some
24 that I give you in error because there's so

7 (Pages 25 to 28)

<p style="text-align: right;">Page 29</p> <p>1 many papers, and it's hard to remember which 2 ones are new and which ones... 3 (Witness reviews document(s).) 4 A. This one's new. 5 (Witness tenders document.) 6 (Whereupon, Exhibit Pramudji-4, 7 "Sling surgery for stress urinary 8 incontinence in women: a systematic 9 review and metaanalysis", was marked for 10 identification.) 11 A. You know, I think without going 12 through my report, it's hard to really 13 remember which ones are which. 14 (Witness tenders document.) 15 (Whereupon, Exhibit Pramudji-5, 16 "Randomized Trial of Tension-Free Vaginal 17 Tape and Tension-Free Vaginal 18 Tape-Obturator for Urodynamic Stress 19 Incontinence in Women", was marked for 20 identification.) 21 BY MS. KIRKPATRICK: 22 Q. Thanks. 23 A. Those I know. 24 MR. SNELL: Just so I'm clear,</p>	<p style="text-align: right;">Page 30</p> <p>1 Counsel, are you asking in addition to 2 the ones that she has in her report, 3 anything beyond that? 4 MS. KIRKPATRICK: What I'm trying 5 to understand is -- you know, we kind of 6 agreed that we're not going to rehash old 7 ground with Lewis, so I don't want to ask 8 about all of the literature out there. 9 I'm asking Dr. Pramudji if she 10 can identify for me what specifically 11 she's relying on here that wasn't covered 12 in Lewis so we can narrow the focus of 13 what we're talking about today. 14 (Whereupon, Exhibit Pramudji-6, 15 "Polypropylene mesh: evidence for lack of 16 carcinogenicity", was marked for 17 identification.) 18 MR. SNELL: Her report has 19 additions, I know that for a fact. What 20 I'm trying to understand is you mean 21 beyond those obvious additions in her 22 report, or -- 23 MS. KIRKPATRICK: Right. What I 24 don't want to do --</p>
<p style="text-align: right;">Page 31</p> <p>1 We can go off the record here. 2 (Recess, 10:28 a.m. to 10:34 a.m.) 3 BY MS. KIRKPATRICK: 4 Q. Okay, Dr. Pramudji. I'm not 5 trying to give you a memory test here. What 6 I'm really just looking for are the primary 7 documents that you can recall that you've 8 relied on, the primarily medical literature 9 that you relied on for your opinions in this 10 TVT-O case versus the TVT case that you 11 identified or that you used in Ms. Lewis's 12 case. 13 A. Okay. 14 Q. And I understand that you have 15 things on your reliance list and cited in 16 your report and that you intend to rely on 17 those. 18 A. Yes. These are a couple others 19 that I don't believe are on the report list 20 that I looked at since that deposition. 21 Q. Okay. Let me take a look at 22 those. 23 A. This one's not specifically about 24 TVT-O, but it's got some useful information</p>	<p style="text-align: right;">Page 32</p> <p>1 in it. 2 (Whereupon, Exhibit Pramudji-7, 3 "Long-Term Results of Burch 4 Colposuspension", was marked for 5 identification.) 6 BY MS. KIRKPATRICK: 7 Q. Okay. Anything else? 8 (Witness tenders document.) 9 (Whereupon, Exhibit Pramudji-8, 10 "Five-year Results of a Randomized Trial 11 Comparing Retropubic and Transobturator 12 Midurethral Slings for Stress 13 Incontinence", was marked for 14 identification.) 15 BY MS. KIRKPATRICK: 16 Q. And if you come across anything 17 later, you can certainly let me know. 18 Okay. Let me just identify these 19 for the record. Exhibit 4 is a medical 20 article entitled, "Sling surgery for stress 21 urinary incontinence in women: a systematic 22 review and metaanalysis." 23 Exhibit 5 is a medical article 24 from the Journal of Urology entitled</p>

Christina Pramudji, M.D.

Page 33

1 "Randomized Trial of Tension-Free Vaginal
2 Tape and Tension-Free Vaginal Tape-Obturator
3 for Urodynamic Stress Incontinence in Women."

4 MR. SNELL: Who is the author on
5 that?

6 MS. KIRKPATRICK: Roderick Teo.

7 Exhibit 6 is from the
8 International Journal of Urogynecology
9 and Pamela Moalli, "Polypropylene mesh:
10 evidence for lack of carcinogenicity,"
11 there we go, got it out.

12 Exhibit 7 is from Gynecologic and
13 Obstetric Investigation. It's entitled,
14 "Long-Term Results of Burch
15 Colposuspension."

16 And Exhibit 8 is from the
17 European Association of Urology,
18 "Five-year Results of a Randomized Trial
19 Comparing Retropubic and Transobturator
20 Midurethral Slings for Stress
21 Incontinence."

22 BY MS. KIRKPATRICK:

23 Q. And those are articles that
24 you're relying on for your opinions in

Page 34

1 Ms. Huskey's case. Is that right?

2 A. That's correct.

3 Q. Okay. Going back to your work
4 specifically for Ethicon, by the time you
5 were retained as an expert for Ethicon in the
6 summer of 2013, you had worked for them for
7 about eight years prior to that in the
8 various roles that we have discussed,
9 correct?

10 A. That's correct.

11 Q. And you had been compensated a
12 significant sum of money for your work with
13 Ethicon prior to your retention as an expert
14 witness in the summer of 2013.

15 MR. SNELL: Form. Okay. Go
16 ahead.

17 A. Well, define "significant." I
18 mean, do you have a specific number in mind
19 that you're referring to?

20 BY MS. KIRKPATRICK:

21 Q. I don't. We can take significant
22 out if you'd like. You've been compensated
23 the amount that you identified --

24 A. Yes.

Page 35

1 Q. -- in your Lewis testimony?

2 A. Okay.

3 Q. And you haven't been compensated
4 beyond that for any other work?

5 A. Correct, yes.

6 Q. Okay, thank you. What
7 specifically were you asked to do in
8 Ms. Huskey's case?

9 A. Well, first I was asked to review
10 the basic medical records, the most pertinent
11 medical records and decide if I felt that I
12 would support the position of Ethicon in this
13 case.

14 And then I was asked to provide
15 my opinion based on all the medical records
16 and depositions that had been taken up to
17 that point to formulate my opinions in regard
18 to that case.

19 Q. And do you know when you were
20 first contacted by Ethicon or their lawyers
21 about Ms. Huskey's case?

22 A. Yes. It was mid February.

23 Q. Mid February of 2014?

24 A. Correct.

Page 36

1 Q. Okay. And what did Ethicon
2 provide you with as of mid February 2014 to
3 allow you to make a decision about whether
4 you supported the position of Ethicon in this
5 particular case?

6 A. I can't remember exactly. I know
7 it included the operative reports. It
8 included Dr. Byrkit's initial evaluation and
9 surgery discussion, Ms. Huskey's deposition
10 and Dr. Byrkit's deposition. I can't
11 remember. There was more, but I can't
12 remember everything.

13 Q. Okay. Did you look at any
14 medical records from Dr. Siddique?

15 A. Yes. Well, the operative
16 reports, and I believe some of the office
17 visits from that.

18 Q. What other medical records do you
19 recall reviewing at the outset to make the
20 initial decision about whether you could
21 support Ethicon's opinions in this case?

22 MR. SNELL: Form.

23 Go ahead.

24 A. I can't recall.

Christina Pramudji, M.D.

Page 37

BY MS. KIRKPATRICK:

Q. Okay. And when did you make the decision that you were willing to serve as an expert witness for Ethicon in this matter?

A. After I reviewed those records.

Q. Okay. And how long did that take you?

A. About a day.

Q. Do you remember who at Ethicon you contacted to say that, yes, you were willing to serve as an expert witness?

A. Mr. Snell.

Q. And was Mr. Snell the person who contacted you in the first instance to ask --

A. Yes.

Q. -- if you would consider being an expert?

Have you discussed Ms. Huskey's case with anybody else at Ethicon besides Mr. Snell?

A. No.

Q. Did you tell Mr. Snell what information you would want to review before making a decision whether to serve as an

Page 39

literature you believed was relevant to your opinions in this case?

A. No, I did not.

Q. And that was -- the literature that you relied on was the literature that was provided to you by Mr. Snell?

A. Yes.

Q. Okay. Did Mr. Snell provide you -- after Mr. Snell had provided medical literature to you, did you go out and research or look for any other types of medical literature to answer any other questions that you may have concerning the issues in this case?

A. Well, I'm always reviewing the literature. I can't say I did a specific search, but I'm always scanning for new information regarding sling and mesh cases. I haven't really found anything else that hasn't been included that I feel like is relevant to my opinions, but I'm always reviewing the literature, looking for all the information that I can regarding the sling and mesh cases.

Page 38

expert witness in this case?

A. Yes.

Q. And did he provide all of that information to you?

A. Yes, he did.

Q. Did he provide any other information to you that he believed would be helpful in formulating your opinion in this case?

A. I'm not sure, but I would think so, because there's a very -- I mean, just numerous medical records and depositions. There's several things.

Q. Did he provide you with any literature?

A. Yes, he did.

Q. Okay. And what literature did he provide you with?

A. Well, he actually helped me with almost all the literature. It's very comprehensive.

Q. Did you do an independent literature review in connection with Ms. Huskey's case to determine what

Page 40

Q. Okay. About how many -- let's take a look at your expert report, which was marked, I think, as Exhibit 2 in this case.

A. Uh-huh.

Q. And marked as Exhibit B to this is a -- one, two, three, four, five, six, seven, eight -- somewhere around 20 pages, give or take a few pages, that are listings of medical literature. Is that correct?

A. Yes.

Q. And this is the medical literature that you've identified about your reliance material in addition to the specific medical articles that you've cited in your report itself, correct?

A. Yes. Yes.

Q. And Mr. Snell provided you with each of these articles?

A. Yes.

Q. And did you read each of these articles?

A. At least I read the abstract on each of them and skimmed through all of them.

Q. And this is -- there's nothing on

10 (Pages 37 to 40)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 41</p> <p>1 this list, apart from the medical articles -- 2 well, I'm sorry, that's a bad question. 3 In addition to that, there are 4 some Ethicon documents that you have 5 identified on here, patient brochures and 6 some other information at the end of the 7 list. Do you see that? 8 A. Yes. The IFU. 9 Q. It includes the IFU, there's 10 slide decks. 11 A. Yes. 12 Q. There's a whole bunch of videos. 13 A. Correct. 14 Q. Is that all information that 15 Mr. Snell provided to you specifically in 16 connection with this case? 17 A. Yes. 18 Q. Did you do any kind of 19 independent research into any other source of 20 information concerning Ethicon or the company 21 at all, or did you rely solely on what 22 Mr. Snell had provided to you? 23 MR. SNELL: Object to form. 24 A. You know, just looking back at</p>	<p style="text-align: right;">Page 42</p> <p>1 some of my own materials that I had, but they 2 were already on the list, yeah. 3 BY MS. KIRKPATRICK: 4 Q. Okay. So it's fair to say that 5 everything that is identified in the last 6 three pages here, which are the Ethicon 7 documents, they're all documents that were 8 provided to you by Mr. Snell in connection 9 with this litigation? 10 A. Yes. 11 Q. Okay. Now, do you believe that 12 it's important, as a physician, to gather as 13 much information as you can about a patient 14 before making a determination of the cause of 15 a medical condition? 16 A. Yes. 17 Q. Okay. And you would consider all 18 of the possible causes of a medical condition 19 when reviewing someone's medical records, 20 correct? 21 A. Yes. 22 Q. That's no substitute, though, for 23 actually test- -- for actually talking to a 24 patient and getting a firsthand account of</p>
<p style="text-align: right;">Page 43</p> <p>1 what their medical condition is, correct? 2 A. Well, yes. I mean, the best 3 thing is to take it all in toto; their 4 history, the records that you have, listening 5 to the patient, and of course, examining the 6 patient. 7 Q. Okay. When did you ask to 8 perform an IME of Ms. Huskey in this case? 9 A. I can't remember when. 10 Q. Did you feel confident generating 11 an expert report in this matter without 12 having had the opportunity to speak with 13 Ms. Huskey and examine her? 14 A. Yes. 15 Q. Okay. 16 A. And I did note in my expert 17 report that I would supplement this, once I 18 did the IME. 19 Q. And you did do that and you 20 provided us with that this week. Is that 21 right? 22 A. Yes. 23 Q. Did the IME change your opinions 24 at all?</p>	<p style="text-align: right;">Page 44</p> <p>1 A. No. 2 Q. How many times have you met with 3 Mr. Snell to prepare for your expert reports 4 and testimony in Ms. Huskey's case? 5 A. Well, we met in person yesterday 6 and we spoke on the phone a handful of times. 7 Q. How long did you meet for 8 yesterday? 9 A. Four hours. 10 Q. Four hours, okay. You performed 11 the IME of Ms. Huskey on what date? 12 A. Last Friday, April 4th. 13 Q. April 4th. 14 A. Yes. 15 Q. Okay. And then you issued the 16 report that we've identified as Exhibit 3 on 17 what day? 18 A. I issued this I believe on 19 April 9th. 20 Q. And that was Wednesday of this 21 week. Is that right? 22 A. Correct. 23 Q. Between Ms. Huskey's IME with you 24 on Friday, April 4th, and the time that you</p>

11 (Pages 41 to 44)

Christina Pramudji, M.D.

Page 45

1 issued your written report identified as
2 Exhibit 3, how many times did you talk to
3 Mr. Snell?
4 A. Once.
5 Q. And how long was that for?
6 A. 15 minutes.
7 Q. Who wrote your IME?
8 A. I did.
9 Q. Did you have any input from
10 anyone else?
11 MR. SNELL: Hold on. You're not
12 answering that. We had an agreement and
13 I didn't ask your experts about the
14 drafting process.
15 MS. KIRKPATRICK: No, I think I
16 can ask her if anyone besides -- you're
17 correct, I shouldn't be asking her if it
18 included you, but I think I can ask her
19 if there's anybody else out there who had
20 input into the report and I think you did
21 that in Dr. Steege's deposition regarding
22 Dr. Carey. So you're right, it's a bad
23 question.
24 MR. SNELL: Okay. So she's

Page 47

1 and expert report in the Lewis case yourself?
2 A. Yes.
3 Q. Did you work with any other
4 experts to prepare or discuss Ms. Huskey's
5 case?
6 A. No.
7 Q. Do you know who is serving as an
8 expert witness for Ethicon besides yourself?
9 A. I know Burt's told me, but I
10 can't remember right now.
11 Q. So besides the communications
12 that you've had with the lawyers for Ethicon,
13 you haven't discussed this case with any
14 other experts or any other physicians or
15 anyone else?
16 A. No.
17 Q. Okay. Now, sitting here today,
18 what we've marked as Exhibit 2 and Exhibit 3
19 contains all of the opinions that you intend
20 to offer in Ms. Huskey's case, correct?
21 A. Those are my primary opinions.
22 There may be some new -- if there's some new
23 information that comes out, there may be new
24 opinions that I would offer at the time of

Page 46

1 asking you besides any discussions with
2 me, she's talking about any other doctors
3 or any other folks.
4 THE WITNESS: Okay.
5 BY MS. KIRKPATRICK:
6 Q. So yes, let me pull that back.
7 A. I understand. Okay.
8 Q. Is there anyone besides Mr. Snell
9 that you talked to or got input on for the
10 IME itself?
11 A. No.
12 Q. Okay. Did you draft your expert
13 report that is identified as Exhibit 2 in
14 this case?
15 A. Yes, I did.
16 Q. And is that all your original
17 work product?
18 A. Yes.
19 Q. How long did it take you to draft
20 that?
21 A. A long time. A lot of it was
22 also carryover from the Lewis case, the
23 general opinions.
24 Q. And did you draft your opinions

Page 48

1 trial.
2 Q. Sitting here today, do you recall
3 any opinions as of whatever date --
4 April 11th, I think it is -- in addition to
5 what has been set forth in your expert report
6 marked as Exhibit 2 and in your IME marked as
7 Exhibit 3?
8 A. No.
9 Q. You haven't discussed any new
10 opinions or reached any new opinions to date.
11 Is that right?
12 A. That's correct.
13 Q. Okay. If you can take a look at
14 Exhibit 1, which is your notice of
15 deposition.
16 A. Sure.
17 Q. And I think you testified that
18 you saw this before today?
19 A. Yes.
20 Q. Okay. When did you see it?
21 A. I don't recall.
22 Q. And attached to the notice of
23 deposition is a Schedule A that identifies a
24 list of things that we asked you to bring

12 (Pages 45 to 48)

Christina Pramudji, M.D.

Page 49

1 with you today to the deposition. Is that
 2 right?
 3 A. Uh-huh.
 4 Q. And -- oh, I think they're gone.
 5 Looks like you brought about five boxes worth
 6 materials?
 7 A. Correct.
 8 Q. Okay. I just want to make sure
 9 that I have this correct for the record.
 10 That material that you brought today includes
 11 all of the materials that you relied on and
 12 that were identified in your Lewis case,
 13 correct?
 14 A. Hmm...
 15 MR. SNELL: I'm going to object
 16 to that. Object to the form.
 17 A. I believe so.
 18 BY MS. KIRKPATRICK:
 19 Q. Okay. And in addition to that,
 20 you've brought information with you that's
 21 relevant to Ms. Huskey's case specifically.
 22 Is that right?
 23 A. Yes.
 24 Q. Can you identify for the record

Page 50

1 what it is that you brought with you today in
 2 response to Schedule A that relates to
 3 Ms. Huskey's case?
 4 A. The medical records and the
 5 depositions, the reports, the IME report. I
 6 believe that's it, that's all.
 7 Q. Okay. Let's talk about the
 8 depositions. I know from looking through the
 9 box earlier, which I appreciate your letting
 10 me do that, that you have a number of
 11 reports -- excuse me, a number of depositions
 12 that were taken of both fact and expert
 13 witnesses in Ms. Huskey's case with you.
 14 A. Yes.
 15 Q. Can you just go through those and
 16 identify them for the record, which ones they
 17 are that you have reviewed in connection with
 18 your testimony and opinions?
 19 A. Uh-huh. Yes.
 20 MR. SNELL: Do you want her to
 21 actually pull the --
 22 A. Do you want me to just look at
 23 the list?
 24 BY MS. KIRKPATRICK:

Page 51

1 Q. Yeah, I mean, you can pull them.
 2 I know there are some depositions that you've
 3 looked at that were not identified.
 4 (Discussion off the record.)
 5 MR. SNELL: I thought there was
 6 another binder.
 7 A. Dr. Byrkit; Sohail Siddique,
 8 S-I-D-D-I-Q-U-E, first name Sohail.
 9 Dr. Elizabeth Mueller, M-U-E-L-L-E-R. Nancy
 10 Davidson. John Steege, S-T-E-E-G-E. I
 11 skimmed Dr. Colleen Fitzgerald.
 12 Dr. Vladimir --
 13 Q. Iakovlev?
 14 A. -- Iakovlev, I-A-K-O-V-L-E-V. Jo
 15 Huskey. Did I say Gretchen Dean already?
 16 Dr. Dele Ogunleye, D-E-L-E, last
 17 name O-G-U-N-L-E-Y-E. Dr. Blaivas,
 18 B-L-A-I-V-A-S. Dr. Bruce Rosenzweig,
 19 R-O-S-E-N-Z-W-E-I-G.
 20 Q. Is there one right under that
 21 too?
 22 A. No, that's Blaivas. I got extra
 23 back.
 24 Q. Okay. And did you review all of

Page 52

1 these depositions in connection with your
 2 testimony here today?
 3 A. Yes, the ones that I said. There
 4 were some that I didn't review in detail.
 5 Q. Okay. I believe you said you
 6 didn't review Dr. Fitzgerald in detail?
 7 A. Right.
 8 Q. Which other ones did you not
 9 review in detail?
 10 A. Dr. Rominger, Dr. Schoenig, Ruth
 11 Teel, Terry Ward and Brian Yocks and Allen
 12 Huskey, James Harms, Michelle Irvin.
 13 Q. Okay. So those are depositions
 14 that you had available to you but you just
 15 skimmed because you didn't think that they
 16 were central to your opinions in the case?
 17 A. Correct.
 18 Q. Do you -- outside of your
 19 connection in this case, do you know any of
 20 the physicians that have treated Ms. Huskey?
 21 A. No.
 22 Q. Do you know any of the physicians
 23 who have offered expert opinions on behalf of
 24 Ms. Huskey?

13 (Pages 49 to 52)

Christina Pramudji, M.D.

Page 53

1 A. No.
2 Q. Do you know any of them by
3 reputation?
4 A. Yes.
5 Q. Who do you know by reputation?
6 A. Jerry Blaivas.
7 Q. And how do you know Dr. Blaivas
8 by reputation?
9 A. From AUA courses and from the
10 literature.
11 Q. And do you consider him an expert
12 on the mesh complications and urology issues?
13 A. No.
14 Q. You do not. Why not?
15 A. I consider him an expert in
16 urology, female urology, but he doesn't have
17 a lot of experience with implanting mesh.
18 Q. But you agree he's got a lot of
19 experience in explanting mesh, don't you?
20 A. In incontinence treatment.
21 Q. In explanting mesh specifically?
22 A. I don't know how much experience
23 he has with that.
24 Q. Did you read his deposition?

Page 55

1 removal of Ms. Huskey's mesh?
2 MR. SNELL: Form.
3 Go ahead.
4 A. I think, yes, that and my
5 experience with mesh in general.
6 BY MS. KIRKPATRICK:
7 Q. Okay.
8 A. Over a thousand slings and
9 Prolift patients.
10 Q. So you've put mesh in about a
11 thousand times. Is that right?
12 A. 15 to -- 1500 to 2000, somewhere
13 in there.
14 Q. Okay. And you've removed mesh
15 from not quite a hundred patients. Is that
16 right?
17 A. Uh-huh.
18 Q. And you also know that you've had
19 patients who have had their mesh removed by
20 other physicians, correct?
21 A. Yes.
22 Q. And how many patients of yours
23 have had their mesh removed by other
24 physicians?

Page 54

1 A. I did.
2 Q. Okay. Do you remember how many
3 he said?
4 A. I don't remember what he said.
5 Q. How many meshes have you removed?
6 A. I would say I've probably done 10
7 to 20 explants, like complete explants. And
8 then I've done multiple revisions or partial
9 removals.
10 Q. And how -- are those SUI related
11 specifically?
12 A. No. They could be pelvic organ
13 prolapse or SUI.
14 Q. Okay. And I think you started to
15 say innumerable and then you went to multiple
16 partial revisions.
17 A. Yeah.
18 Q. Can you give me a ballpark on
19 those?
20 A. Sure. I'm going to say probably
21 around 50 to 60, somewhere in that range.
22 Q. And do you think that work in
23 removing SUI devices qualifies you to testify
24 as an expert here on issues related to the

Page 56

1 A. I know of two.
2 Q. Okay. You know of two
3 specifically?
4 A. Yes.
5 Q. But you'd agree with me there's
6 probably more than that?
7 MR. SNELL: Form.
8 A. I don't know.
9 BY MS. KIRKPATRICK:
10 Q. Okay. In addition to
11 Dr. Blaivas, are there any of the other
12 experts that you know by reputation?
13 A. Elizabeth Mueller. Well, she's
14 not an expert, she was a fact witness.
15 Q. Okay. And what do you know about
16 Dr. Mueller?
17 A. She's involved in a lot of
18 studies related to incontinence and prolapse.
19 Q. Okay. Anyone else?
20 A. No.
21 Q. Okay. Let's try to move pretty
22 quickly through Schedule A, if we can.
23 A. Yes.
24 Q. We asked you to bring records

14 (Pages 53 to 56)

Christina Pramudji, M.D.

Page 57

1 related to your fees, billing or time spent.
2 I think you told me already you haven't
3 generated a bill related to Ms. Huskey's
4 case. Is that right?

5 A. That's correct.

6 MS. KIRKPATRICK: Burt, when
7 that's generated for Ms. Huskey's case --

8 MR. SNELL: I'll give it to you,
9 of course.

10 BY MS. KIRKPATRICK:

11 Q. All right. We asked you to bring
12 an updated copy of your CV. Is the copy that
13 was provided with your expert deposition the
14 most up-to-date copy of that CV?

15 A. Yes, it is.

16 Q. I'll go through that in a minute
17 with you.

18 We asked you to bring with you
19 all documents, including but not limited to
20 videotapes, recordings, databases, whether
21 preliminary or final, prepared by or at your
22 direction in connection with your expected
23 testimony or in connection with the
24 development of an opinion or belief, or an

Page 59

1 been compensated by Ethicon, correct?

2 A. Yes. He wanted the consulting
3 agreements and the record of compensation so
4 I provided everything that I had related to
5 that.

6 Q. So everything that Mr. Kountze
7 has brings us up to date and current on that
8 request?

9 A. That's correct.

10 MR. SNELL: And I'll just make a
11 note for the record it was provided to
12 MDL liaison counsel as well. It was
13 provided to multiple people.

14 MS. KIRKPATRICK: I just want to
15 know where to get it. So I can get it
16 from --

17 MR. SNELL: MDL liaison counsel
18 has the payments, all of that stuff.

19 MS. KIRKPATRICK: MDL liaison
20 counsel or --

21 MR. SNELL: Jeff Kuntz, Bryan
22 Aylstock, they were all sent that.

23 MS. KIRKPATRICK: Okay. So the
24 leads for Ethicon specifically had them,

Page 58

1 assessment or determination of facts,
2 relating to this or any other pelvic mesh
3 cases.

4 Did you bring anything else
5 responsive to that?

6 A. Just -- the boxes that I brought
7 include everything.

8 Q. Is there any specific information
9 that you have that is responsive to the
10 requests in Schedule A that you did not bring
11 with you today?

12 A. On this whole list?

13 Q. Yeah. I just want to see if
14 there's anything that wasn't provided.

15 A. Okay. I'm trying to think. So I
16 believe we are going to -- you know, I know
17 at the last deposition he asked for the
18 records of compensation from Ethicon and you
19 were going to be able to get that from him,
20 so everything else is comprehensive.

21 Q. And what you're talking about
22 there is that after your Lewis deposition,
23 you provided records to Mr. Kountze
24 concerning the amount of money that you've

Page 60

1 that's great.

2 MR. SNELL: Yeah. Also
3 Dr. Pramudji produced documents,
4 communications between her and Ethicon
5 that were --

6 THE WITNESS: Oh, that's right,
7 all those emails. There weren't that
8 many, but I had to go through them.

9 MR. SNELL: That production was
10 made on the MDL plaintiffs' counsel as
11 well.

12 BY MS. KIRKPATRICK:

13 Q. Okay. And that was a production
14 that you made in connection with the Lewis
15 case, correct?

16 A. Correct.

17 Q. Is there anything else that you
18 have generated, any other communications you
19 have had with Ethicon outside of your work as
20 an expert witness?

21 A. No.

22 Q. There's no other communications?

23 A. No.

24 Q. There's no other emails?

15 (Pages 57 to 60)

Christina Pramudji, M.D.

Page 61

1 A. No.
2 Q. There's no other billings or
3 anything like that?
4 A. That's correct.
5 Q. So what I can get from them will
6 be the complete copy?
7 A. Yes.
8 Q. Okay, great. Is there anything
9 else that you did not bring with you today --
10 A. No.
11 Q. -- that would be responsive to
12 this subpoena?
13 Okay. Is there anything here --
14 well, we can talk about that off the record.
15 Okay, Dr. Pramudji. You are a
16 urologist, correct?
17 A. Correct.
18 Q. And there's a difference between
19 being a urologist and a urogynecologist,
20 isn't there?
21 A. Yes, there is.
22 Q. Can you describe the difference
23 for me, please?
24 A. Yes. A urologist has six years

Page 63

1 not feel the need to do a fellowship because
2 I had excellent training with them.
3 Q. And you're talking about
4 specifically a fellowship in urogynecology?
5 A. Or we call it a female urology
6 fellowship from coming out of urology.
7 Q. Female urology, okay.
8 And you felt that the training
9 that you had received during your residency
10 qualified you to do -- to focus your
11 attention on female urology issues without
12 going through that fellowship?
13 A. Yes.
14 Q. How long have you treated women
15 with stress urinary incontinence?
16 A. Including residency, 16 years.
17 Q. When did you start using
18 polypropylene slings to treat women with
19 stress urinary incontinence?
20 A. I was trained on it in residency,
21 2001, and then I used it in private practice
22 starting in 2002 when I first began as a
23 practitioner.
24 Q. Okay. And in 2002, the only

Page 62

1 of surgical training centered around the
2 urinary tract, and there is also pelvic floor
3 training in that as well. We do major
4 surgery such as bladder removal,
5 reconstruction, kidney removal, very detailed
6 reconstruction of the urinary tract.
7 Now, there is -- I'm sure you're
8 aware, the Female Pelvic Medicine and
9 Reconstructive Surgery board, which I did sit
10 for, based on my experience, and passed,
11 which is basically the same thing as
12 urogynecology, minus the hysterectomy. I do
13 not do hysterectomies but I do everything
14 else that a urogynecologist would do.
15 Q. Okay.
16 A. A urogynecologist does a
17 four-year obstetrics and gynecology residency
18 so they only have approximately two years of
19 surgical training and then they have a
20 fellowship of three years, and it's centered
21 around the pelvic floor.
22 But in my training, I worked with
23 Drs. Rodney Appell and Timothy Boone, who are
24 very renowned female urologists, and I did

Page 64

1 polypropylene sling kits that were on the
2 market were implanted using the retropubic
3 method. Is that right?
4 A. That's correct.
5 Q. So you were trained in your
6 residency to implant a retropubic sling?
7 A. Yes.
8 Q. And when you started in private
9 practice, you continued to implant the
10 retropubic sling. Is that right?
11 A. That's right.
12 Q. What brand did you use?
13 A. I'm sorry, what?
14 Q. What brand?
15 A. The Ethicon.
16 Q. Have you ever implanted anything
17 besides Ethicon?
18 A. Yes.
19 Q. Which ones have you used?
20 A. AMS, Caldera, C-A-L-D-E-R-A,
21 Boston Scientific. I think that's all.
22 Q. And at the time you started using
23 these in your practice in 2002, did you
24 believe that the retropubic was an effective

Christina Pramudji, M.D.

Page 65

1 way to treat women with stress urinary
2 incontinence?

3 A. Yes, very effective and very safe
4 and much less invasive than what we had been
5 doing for incontinence.

6 Q. Okay. Let's talk about that a
7 little bit, going back to 2002. When you say
8 that it was safe, did you rely on medical
9 literature at the time to convince yourself
10 that it was safe?

11 A. Absolutely. It was a big debate,
12 you know, at residency, because -- and we
13 were, you know, carefully looking at the
14 literature at that time because it was a new
15 procedure. Members of my faculty were
16 skeptical, so we were, you know, looking at
17 it carefully.

18 Q. Now, at the time that you started
19 implanting these, the kits to treat stress
20 urinary incontinence had been on the market
21 for about four years. Is that right?

22 A. That sounds about right.

23 Q. Okay. And you know that there
24 were no clinical trials done prior to the

Page 67

1 club.

2 Q. But the one that stands out to
3 you was the Ulmsten study. Is that right?

4 A. Well, that was in response to
5 your question that there were no studies
6 prior to the launch.

7 Q. Okay. So in addition to the
8 Ulmsten study, which obviously you do recall,
9 what other studies do you remember looking
10 at, if any?

11 A. I don't remember.

12 Q. Were any of the studies that you
13 looked at at the time designed to look at the
14 long-term safety of the product when
15 implanted permanently in women?

16 A. Well, at that point I think they
17 didn't have more than maybe four- or
18 five-year data, so I can't recall.

19 Q. Okay. So we agree that the
20 maximum amount of time that could have been
21 looked at at that time is probably about four
22 to five years?

23 A. Correct.

24 Q. Do you recall whether any of the

Page 66

1 launch of the TVT Classic. Isn't that right?

2 MR. SNELL: Form, misstates the
3 evidence.

4 A. There were trials.

5 MR. SNELL: Foundation, too, for
6 that one.

7 BY MS. KIRKPATRICK:

8 Q. Which ones did you rely on?

9 A. The ones in Europe that were done
10 with Ulmsten and...

11 Q. Okay. So the Ulmsten, so that
12 was what you relied on for the safety?

13 A. Uh-huh.

14 Q. Anything else besides the Ulmsten
15 studies?

16 A. Are you talking about what I
17 relied on in 2000?

18 Q. I just want to know what it was
19 that you had looked at to convince yourself
20 that this was safe.

21 A. I can't remember. There was
22 multiple studies that -- there was always
23 something coming out in the Journal of
24 Urology that we would look at, at journal

Page 68

1 studies that you looked at, however, were
2 designed to look at the issue of safety as
3 opposed to efficacy?

4 A. I don't recall. But I would
5 think that there were, because that was our
6 big question, is this going to be safe to put
7 in, polypropylene mesh in women, into their
8 vaginal area; so that was definitely on the
9 forefront of our minds. Baylor residency,
10 top residency program, we were all really
11 looking at that carefully, and the conclusion
12 was that it was safe.

13 Q. But you don't recall any studies
14 that were specifically designed to look at
15 the issue of safety?

16 MR. SNELL: Form.

17 A. That was too long ago. I can't
18 specifically say any specific studies.

19 BY MS. KIRKPATRICK:

20 Q. And you'll agree with me, even if
21 those -- if those studies did exist, the
22 maximum amount of time they would have been
23 looking at was about four to five years?

24 A. Yes.

17 (Pages 65 to 68)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 69</p> <p>1 Q. Do you have any concerns with</p> <p>2 using the retropubic approach to implant a</p> <p>3 polypropylene sling?</p> <p>4 A. I'm sorry, could you repeat that</p> <p>5 question?</p> <p>6 Q. Did you have any concerns about</p> <p>7 the safety of using a retropubic device to</p> <p>8 treat stress urinary incontinence?</p> <p>9 A. Well, it has to be done properly.</p> <p>10 I think it's been well established that if it</p> <p>11 is done properly and in an appropriate</p> <p>12 patient, that it is safe. The risk to</p> <p>13 benefit ratio is quite favorable for women.</p> <p>14 Q. Okay. What do you mean by "done</p> <p>15 properly"?</p> <p>16 A. Following surgical principles,</p> <p>17 following the recommended guidelines for use.</p> <p>18 Q. And when you're talking about</p> <p>19 that, are you talking about the instructions</p> <p>20 for use that, for example, Ethicon will</p> <p>21 publish with the kits themselves?</p> <p>22 A. That's part of it, but also just</p> <p>23 applying general surgical principles that</p> <p>24 we're taught in residency.</p>	<p style="text-align: right;">Page 70</p> <p>1 Q. Okay. Anything else that you</p> <p>2 mean by "if done properly"?</p> <p>3 A. Well, I mean, for me, I think</p> <p>4 there needs to be that just basic surgical</p> <p>5 attention to detail, meticulous handling of</p> <p>6 the tissues, and I think it's important to</p> <p>7 just be aware of each step that you're doing</p> <p>8 in a surgical procedure.</p> <p>9 Q. Okay. Thank you.</p> <p>10 And you also had said that in</p> <p>11 appropriate candidates.</p> <p>12 A. Uh-huh.</p> <p>13 Q. Who would not be an appropriate</p> <p>14 candidate for the implantation of a</p> <p>15 retropubic polypropylene midurethral sling?</p> <p>16 A. Well, a patient that does not</p> <p>17 have healthy enough tissue, if their tissue</p> <p>18 is very thinned out, so there might be</p> <p>19 concerns about how they might heal.</p> <p>20 Q. Uh-huh.</p> <p>21 A. Or they do not have, of course,</p> <p>22 documented stress urinary incontinence,</p> <p>23 either by their history or by urodynamics; if</p> <p>24 they have only urge incontinence, of course</p>
<p style="text-align: right;">Page 71</p> <p>1 that wouldn't be appropriate.</p> <p>2 Q. And of course it wouldn't be</p> <p>3 appropriate if they had neither stress</p> <p>4 urinary incontinence nor urge urinary</p> <p>5 incontinence, correct?</p> <p>6 A. Yeah. Yeah, of course.</p> <p>7 Q. So you need to have a diagnosis</p> <p>8 of the condition before it would be</p> <p>9 appropriate.</p> <p>10 A. Yes.</p> <p>11 Q. Okay. So apart from women who</p> <p>12 don't have SUI and women who may not have</p> <p>13 healthy tissue, is there any other</p> <p>14 contraindication that you believe exists for</p> <p>15 who would be an inappropriate candidate for a</p> <p>16 retropubic synthetic sling?</p> <p>17 MR. SNELL: Form.</p> <p>18 A. Not as a general category.</p> <p>19 BY MS. KIRKPATRICK:</p> <p>20 Q. Okay. How many retropubic</p> <p>21 devices have you implanted, approximately?</p> <p>22 A. I think the number is around 300.</p> <p>23 Q. About 300 total?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 72</p> <p>1 Q. And of the 300 patients that</p> <p>2 you've implanted a retropubic device, can you</p> <p>3 give me a ballpark of how many you've had to</p> <p>4 remove or excise the device from? Do you</p> <p>5 remember?</p> <p>6 A. It's going to be a very low</p> <p>7 number. I don't -- I mean, honestly, one or</p> <p>8 two that I would remove it.</p> <p>9 Now, if there's a mesh exposure,</p> <p>10 if you're referring to that category as well,</p> <p>11 that's probably about a half a percent rate</p> <p>12 for my patients.</p> <p>13 Q. So half a --</p> <p>14 A. So 1 out of 200.</p> <p>15 Q. So 1 out of 2- -- so you think</p> <p>16 that you've got probably one to two patients</p> <p>17 that you've actually had to go in and remove</p> <p>18 the sling and you've probably got one or two</p> <p>19 other patients that you've had to go and</p> <p>20 excise the mesh if there's an erosion. Is</p> <p>21 that correct?</p> <p>22 A. Partially, yes.</p> <p>23 Q. Okay. Why did you have to remove</p> <p>24 the mesh in the one or two patients? Do you</p>

18 (Pages 69 to 72)

Christina Pramudji, M.D.

Page 73

1 remember what the complications were?
2 A. I can't remember the details.
3 Q. Do you have a general memory?
4 A. No.
5 Q. What are the circumstances in
6 which you, as a physician and as a surgeon,
7 would choose to remove a retropubic
8 polypropylene sling from a patient?
9 A. If they're having significant
10 voiding dysfunction and obstruction and the
11 sling really isn't effective, then I might go
12 in and remove the part of the sling that's
13 around the urethra, so a urethrolisis.
14 Or if they have a mesh exposure
15 that can't be managed just with a small
16 revision, then I might need to go ahead and
17 take out the sling that's around the urethra
18 and in the vagina.
19 Q. Okay. Anything else?
20 A. No.
21 Q. Okay. Now, at some point you
22 began to use a transobturator sling as
23 opposed to a retropubic, correct?
24 A. Yes.

Page 75

1 different area.
2 BY MS. KIRKPATRICK:
3 Q. And the mesh actually sits in a
4 different part of the pelvic cavity. Isn't
5 that right?
6 A. That's correct.
7 Q. Okay. Before you started
8 implanting TVT-O slings, had you performed
9 any surgery in the transobturator space in a
10 woman?
11 A. No.
12 Q. Is there any other surgery that
13 you perform as a urologist that occurs in the
14 transobturator space of a woman?
15 A. No.
16 Q. Why did you change from using a
17 retropubic to using a transobturator
18 approach?
19 MR. SNELL: Form.
20 A. The TVT Classic had more of a
21 risk of bladder perforation compared to TVT-O
22 and it took longer to do.
23 BY MS. KIRKPATRICK:
24 Q. How long did it take to do the

Page 74

1 Q. And if I remember correctly, is
2 that about 2006?
3 A. Yes. Maybe -- I think it was
4 before that.
5 Q. Before that?
6 A. Yeah.
7 Q. When did you start to do that?
8 A. I think it was 2004.
9 Q. 2004, okay. And what was the
10 first transobturator midurethral
11 polypropylene sling that you used?
12 A. The TVT-O.
13 Q. And you agree with me that the
14 TVT Classic and the TVT-O are made with the
15 same material, correct?
16 A. That's correct.
17 Q. But they're inserted into women
18 differently, correct?
19 A. Correct.
20 Q. And they go through different
21 parts of their anatomy in the insertion
22 process?
23 MR. SNELL: Form.
24 A. The trocar does go through a

Page 76

1 TVT Classic?
2 A. About 20 minutes.
3 Q. And how long does it take to do
4 the TVT-O?
5 A. About 10 minutes.
6 Q. So about a 10-minute -- okay.
7 What information did you rely on
8 in making a decision to use the new surgical
9 technique of implanting a polypropylene
10 midurethral sling through the transobturator
11 space?
12 A. I looked at the literature that
13 was available at that time, and I can't
14 remember specifically what it was. I
15 apologize. But to show that it was as
16 effective, because that was my concern, that
17 it was going to be as effective as the TVT.
18 It's faster, less risk of bladder
19 perforation, but is it going to work as well.
20 Q. Okay. And you looked at the
21 medical literature at the time and satisfied
22 yourself that it was going to be equally
23 effective?
24 A. Yes.

19 (Pages 73 to 76)

Christina Pramudji, M.D.

Page 77

1 Q. What, if anything, did you do to
2 examine or consider what complications may
3 arise from the use of a midurethral sling
4 through the transobturator approach as
5 opposed to the retropubic approach?

6 A. Well, the initial literature that
7 was available that would report the
8 complications that they experienced. Also
9 talking to other pelvic floor surgeons that
10 had used it.

11 Q. Okay. And you'll agree with me
12 as well that as far as long-term
13 complications associated with use of a
14 transobturator midurethral polypropylene
15 sling that there was relatively limited data
16 available at the time in 2004, correct?

17 A. That's correct.

18 Q. So you would have looked at both
19 the efficacy and you would have looked at
20 what you considered to be the short-term
21 complications that may arise that would have
22 been reflected in medical literature.

23 A. That's correct.

24 Q. Did you talk to anyone at Ethicon

Page 78

1 about it?

2 A. Yes.

3 Q. Okay. Who did you talk to?

4 A. The sales rep.

5 Q. Uh-huh. Anyone else?

6 A. No.

7 Q. Did Ethicon provide you with any
8 information that informed or helped you make
9 a decision to start using the transobturator
10 approach?

11 A. No.

12 Q. How did you get trained to do it?

13 A. My partner, Dr. Anhalt, he went
14 to a course and then he came back and trained
15 me.

16 Q. Talking about the literature
17 that's out there, you agree with me that
18 there's different types of studies that can
19 be done to look at both issues of safety and
20 efficacy in medical devices, correct?

21 A. Correct. You can do a
22 prospective study, a randomized study, a
23 retrospective study; so there's several
24 different ways that you can look at it.

Page 79

1 Q. So you can do a prospective
2 study, a retrospective study, randomized --

3 A. Randomized controlled trial, you
4 can just look at a cohort of patients.

5 Q. You could look at also, I guess,
6 individual case reports.

7 MR. SNELL: Form.

8 A. Correct.

9 BY MS. KIRKPATRICK:

10 Q. What do you think are the best
11 type of studies that can be done to establish
12 the safety of a medical device?

13 A. Well, a randomized controlled
14 trial is considered the top tier of medical
15 evidence, but it's the hardest study to do.

16 Q. And when you say it's the hardest
17 study to do, what do you mean?

18 A. It's hard, especially for
19 surgical studies, to have patients trust in
20 the roll of the dice as far as what procedure
21 they're going to have ahead of time, because
22 they don't know exactly what they're getting
23 into ahead of time.

24 So there have been studies that

Page 80

1 have not worked out, not specifically related
2 to slings, but in surgery in general, where
3 they couldn't accrue patients.

4 Q. Okay. And you would agree with
5 me that's because in randomized controlled
6 studies, most patients want to have a say in
7 what kind of medical/surgical intervention
8 they're going to have, correct?

9 A. They want to know what they're
10 getting into, yes.

11 Q. And they want to know what the
12 potential complications or potential side
13 effects are from a certain procedure. Is
14 that right?

15 A. Correct.

16 Q. And they want to know what the
17 potential efficacy of the procedure is,
18 correct?

19 A. Correct. But part of that's why
20 you're doing the study, so yeah.

21 Q. Yeah. And those patients also,
22 I'll put it in my everyday speak and the
23 non-medical speak, but they kind of want to
24 have some assurance that they're not going to

20 (Pages 77 to 80)

Page 81

1 end up worse off than they were when they
2 went into this trial. Isn't that right?

3 MR. SNELL: Form.

4 A. I think everybody wants that when
5 they go into surgery, yes.

6 BY MS. KIRKPATRICK:

7 Q. And they want to have some kind
8 of feeling that they're not a human guinea
9 pig in some kind of big surgical experiment.
10 Isn't that right?

11 MR. SNELL: Objection.

12 A. Yes.

13 BY MS. KIRKPATRICK:

14 Q. And so that information is all
15 particularly important to people in making a
16 decision about whether to have a surgical
17 procedure, which is, as you say, one of the
18 limitations of an RCT, correct?

19 A. Correct.

20 Q. What would be the next tier down
21 from an RCT?

22 A. The next tier down would be a
23 prospective study where you're evaluating the
24 results as they come in.

Page 83

1 patients, even examining patients, having
2 them come back in a few years later and
3 looking at where they are right now.

4 Q. Okay. And you will agree with me
5 that when you're talking about a permanent
6 medical implant, it's important to look at
7 long-term clinical effects, correct?

8 A. I think, you know, when you can,
9 obviously, yes. However, you know, you can't
10 necessarily hold a device for 10 years while
11 you're waiting for long-term studies.

12 Q. Okay.

13 A. If you see initial results that
14 demonstrate safety and efficacy, then if
15 the -- you know, if the benefit outweighs the
16 risk, then you proceed forward and then you
17 continue to follow and collect data, which is
18 what I think we've seen with the TVT and the
19 TVT-O, that over, you know, all these years
20 that we've seen thousands of studies that
21 show that or that bear out the safety that
22 was initially seen when it was first
23 beginning to be implanted.

24 Q. Okay. So I want to talk a little

Page 82

1 Q. And so those are studies in which
2 the device has already been implanted. Is
3 that right?

4 A. Typically, yes.

5 Q. And now you're monitoring a
6 series of patients to see what happens after
7 you put the device in.

8 A. Correct.

9 Q. Okay. And then what is next
10 after that?

11 A. And then a retrospective study.

12 Q. Okay. And can you describe what
13 that is?

14 A. That's looking back at your data
15 that you have collected.

16 Q. Okay. So it's like a data
17 analysis, correct?

18 A. Correct.

19 Q. And you'd run like a statistical
20 modeling to see what trends you can discern
21 from the pool of data that you already have
22 in your possession.

23 A. It can include that, it can
24 include questionnaires of patients, calling

Page 84

1 bit about risk-benefit because you just
2 brought this up.

3 A. Uh-huh.

4 Q. There's risk-benefit as it
5 applies in the medical literature, which
6 would be what you're discussing, correct?
7 Does the benefit of this product outweigh the
8 risk. That's a different analysis than what
9 an individual patient goes through to make a
10 decision in her particular case whether the
11 benefit outweighs the risk, correct?

12 MR. SNELL: Form.

13 A. Well, to some degree, yes,
14 because each patient is individual. Each
15 patient has different goals and different --
16 their health is at a different point,
17 different ages, so as far as the literature,
18 we have to look at the whole picture, the
19 whole body of evidence to make a decision
20 about different devices or drugs or what have
21 you.

22 But, yeah, for each patient, it
23 is. It's a discussion with her doctor and a
24 decision about the risks versus the benefits.

<p style="text-align: right;">Page 85</p> <p>1 BY MS. KIRKPATRICK:</p> <p>2 Q. Right. And so every patient is</p> <p>3 entitled to make her own decision about</p> <p>4 whether the potential risks are acceptable in</p> <p>5 her particular situation, correct?</p> <p>6 A. Correct.</p> <p>7 Q. And in order to make that</p> <p>8 determination, you'll agree with me that a</p> <p>9 patient has to be informed of all of the</p> <p>10 risks of a procedure, correct?</p> <p>11 MR. SNELL: Form.</p> <p>12 A. Well, it's impossible, really, to</p> <p>13 inform a patient of all the risks of each</p> <p>14 procedure.</p> <p>15 BY MS. KIRKPATRICK:</p> <p>16 Q. Okay. So how do you decide which</p> <p>17 risks you're going to tell your patients</p> <p>18 about and which ones you're not?</p> <p>19 A. Well, for me, and I think for</p> <p>20 most physicians, you evaluate that patient</p> <p>21 and, you know, where they are and how they're</p> <p>22 going to respond to the therapy, tell them</p> <p>23 about any specific risks that they're at</p> <p>24 higher risk for or that would be more</p>	<p style="text-align: right;">Page 86</p> <p>1 pertinent to their life, and also the main</p> <p>2 risks that are seen in this procedure or any</p> <p>3 procedure.</p> <p>4 Q. Okay. And when you talk about</p> <p>5 main risks, there's two parts to that</p> <p>6 equation. The first is you look at just the</p> <p>7 statistical incidence of that risk over the</p> <p>8 population. Is that right?</p> <p>9 A. Correct.</p> <p>10 Q. But you also look at the severity</p> <p>11 of the potential complication, correct?</p> <p>12 A. Correct. There's -- it's graded</p> <p>13 as far as a serious event or a minor event.</p> <p>14 Q. Okay. So you could have a</p> <p>15 serious adverse event that happens in a very</p> <p>16 small, small percentage of the population,</p> <p>17 but it would be important to tell a woman</p> <p>18 that so she can make the decision whether the</p> <p>19 risk of that particular serious injury is</p> <p>20 relevant to her case and her decision,</p> <p>21 correct?</p> <p>22 A. If there's a specific reason with</p> <p>23 that patient why you would tell her that,</p> <p>24 then yes. But for every patient, you don't</p>
<p style="text-align: right;">Page 87</p> <p>1 need to tell them about every serious</p> <p>2 potential adverse event.</p> <p>3 Q. Well, let me use an example for</p> <p>4 you. When you go in to do surgery, do you</p> <p>5 always warn your patients that there's a risk</p> <p>6 of death with surgery?</p> <p>7 A. Personally, I do not.</p> <p>8 Q. You do not?</p> <p>9 A. But I know a lot of surgeons that</p> <p>10 do, yeah.</p> <p>11 Q. Okay. How do you decide who gets</p> <p>12 the warning about the risk of death from</p> <p>13 surgery and who doesn't?</p> <p>14 A. Well, I typically don't operate</p> <p>15 on patients with much of a risk of death. I</p> <p>16 mean, I can warn them of that when they're</p> <p>17 leaving my office, there's a risk of death</p> <p>18 when you drive home, because there's actually</p> <p>19 more risk of that than with the surgery that</p> <p>20 I do.</p> <p>21 However, if there's a patient</p> <p>22 that's high-risk for kidney removal or if</p> <p>23 they just have a lot of major issues, then I</p> <p>24 would warn them of the risk of death.</p>	<p style="text-align: right;">Page 88</p> <p>1 But from the surgeries that I do,</p> <p>2 the risk of death is so small that -- I mean,</p> <p>3 and also it's kind of obvious if you're going</p> <p>4 to surgery, you know, that some strange event</p> <p>5 could happen and you could die.</p> <p>6 Q. Nobody likes to think of that,</p> <p>7 but you're right.</p> <p>8 So what I'm trying to understand</p> <p>9 here is -- and maybe let me ask it like this.</p> <p>10 A. Okay.</p> <p>11 Q. When you have a patient who comes</p> <p>12 in to get a TVT-O implanted, are there</p> <p>13 certain patients that you warn that there's a</p> <p>14 risk of chronic pain?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. Who would those patients</p> <p>17 be?</p> <p>18 A. Well, most all patients, but, you</p> <p>19 know, particularly if it's a younger patient,</p> <p>20 they tend to have, in my experience, and I</p> <p>21 don't know that this has been borne out in</p> <p>22 the literature, but older patients don't seem</p> <p>23 to have as much pain issues in their pelvic</p> <p>24 area. I don't think their nerves are as</p>

Christina Pramudji, M.D.

Page 89

1 sensitive.

2 So definitely with younger
3 patients and sexually active patients, I will
4 warn them that that is a very small risk, but
5 it is a risk.

6 Q. Okay. What do you consider to be
7 a small risk?

8 A. Oh, like 1 in 500.

9 Q. Okay. And do you reach that
10 statistic from -- or rely on any medical
11 literature in reaching the statistic that
12 approximately 1 in 500 women who are
13 implanted with a TVT-O may experience chronic
14 pain?

15 A. I think that the studies that
16 look at chronic pain show that it is very --
17 I mean, it's hardly reported at all because
18 it's so rare.

19 Q. Okay.

20 A. And in my experience, I don't
21 think I've seen any patient that had that
22 from a TVT-O.

23 Q. Okay. So you haven't personally
24 treated physicians [sic]. Can you identify

Page 90

1 any particular studies that you have in mind
2 that you're relying on to support your
3 opinion that it's extremely rare to have
4 chronic pain following the implantation of a
5 TVT-O device?

6 A. I could look through the studies.
7 I don't have them at my fingertips, but I
8 could look through them.

9 Q. Would glancing through what you
10 have in your report help, or -- I don't want
11 to send you on an exercise of reading 500
12 articles, but if there's anything that jumps
13 out at you, I just would like to know what
14 those are.

15 A. Uh-huh.

16 (Witness reviews document(s).)

17 A. Well, specifically for
18 dyspareunia, dyspareunia, even in the
19 short-term, was rare in the Schimpf study.
20 BY MS. KIRKPATRICK:

21 Q. Can you spell that for the court
22 reporter?

23 A. Yes, S-C-H-I-M-P-F.

24 Q. Would that be what we've

Page 91

1 identified as Exhibit 4? Is that what you're
2 referring to?

3 A. Yes.

4 Q. Okay, great.

5 (Witness reviews document(s).)

6 A. I can't remember the others right
7 now. I'd have to go through -- go through my
8 binders.

9 Okay, here's one. Athanasiou,
10 A-T-H-A-N-A-S-I-O-U, he said no -- they said
11 no patient reported persistent groin pain at
12 the long-term follow-up.

13 And really, looking at the
14 literature, there's really no mention of
15 dyspareunia, groin pain. As far as, you
16 know, persistent vaginal or pelvic pain,
17 there's really not a lot of that. I mean,
18 it's hardly mentioned at all in the
19 literature.

20 BY MS. KIRKPATRICK:

21 Q. Okay.

22 A. And not -- you know, not really
23 seen in practice.

24 Q. In your practice?

Page 92

1 A. Uh-huh.

2 Q. Okay. Let's go back to the
3 discussion of just some general principles
4 about the literature.

5 What does primary endpoint mean
6 in the literature and designing a trial?

7 A. So the primary endpoint is when
8 the study is designed, they're looking at the
9 first thing that they want to evaluate. So,
10 for instance, the subjective cure rate of
11 stress urinary incontinence at one year would
12 be the primary endpoint.

13 And then secondary would be the
14 other side effects, the other complications
15 that were observed in the study.

16 Q. So am I correct -- oh, do you
17 need to grab that?

18 A. No, it's okay.

19 Q. So what happens when one is
20 conducting one of these trials, there's a
21 primary purpose, for example, to establish
22 the efficacy of a particular device, correct?

23 A. Correct.

24 Q. And while doing that study,

23 (Pages 89 to 92)

Christina Pramudji, M.D.

Page 93

1 there's other information that you may gather
 2 along the way that are relevant to other
 3 considerations, correct?
 4 A. Correct.
 5 Q. But the trial is designed with
 6 that primary endpoint in mind, correct?
 7 A. Correct.
 8 Q. Do you -- are you aware of any of
 9 the trials that you have -- or, excuse me,
 10 any of the literature that you relied on that
 11 have a primary endpoint of safety as opposed
 12 to efficacy?
 13 A. Yes. Where is that...
 14 (Witness reviews document(s).)
 15 A. Okay, here's one of them. The
 16 Collinet, C-O-L-L-I-N-E-T.
 17 Did you say specifically for the
 18 TVT-O or TVT?
 19 Q. Well, let's establish that.
 20 We've agreed with me that the TVT-O approach
 21 differs from the retropubic approach,
 22 correct?
 23 A. Yes.
 24 Q. And so because they're different

Page 94

1 surgeries, they have different types of
 2 complications associated with them, correct?
 3 MR. SNELL: Form.
 4 A. A couple of the complications
 5 are -- one of the complications is different.
 6 BY MS. KIRKPATRICK:
 7 Q. Okay. So in order to determine
 8 what the complications associated with the
 9 transobturator approach, we'd need to be
 10 looking at either TVT-O or transobturator
 11 studies, correct?
 12 MR. SNELL: Form again.
 13 A. Correct.
 14 BY MS. KIRKPATRICK:
 15 Q. Okay. So do you see anything in
 16 there related specifically to transobturator
 17 that was designed with the end purpose of
 18 measuring the safety of a transobturator
 19 midurethral sling?
 20 A. Okay.
 21 (Witness reviews document(s).)
 22 A. Here's one that compares TOT to
 23 TVT, Ross. They were mainly looking at
 24 safety.

Page 95

1 BY MS. KIRKPATRICK:
 2 Q. And that was a primary endpoint
 3 of safety?
 4 A. Yes, comparing the two
 5 procedures. That was one of the primary
 6 endpoints. Oh, and Seratti, that's the one
 7 I've been looking for. "Efficacy, adverse
 8 effects and prognostic factors at 5-year
 9 follow-up," Seratti, S-E-R-A-T-T-I.
 10 (Witness reviews document(s).)
 11 A. Those are the ones that I can
 12 find at this moment that kind of focus on
 13 safety, but I think there's more.
 14 BY MS. KIRKPATRICK:
 15 Q. Okay. Well, you know, it's not
 16 meant to be a memory test.
 17 A. Okay, thank you.
 18 Q. Let me just ask you just a couple
 19 of questions. Now, that Collinet that you
 20 cited, that's not an RCT, is it? It's
 21 actually a registry.
 22 A. That's correct. It's a French
 23 registry, uh-huh.
 24 Q. Okay. And so that's one of the

Page 96

1 retrospective studies that we had talked
 2 about, kind of the third tier down on the --
 3 A. I'd have to look at it to -- but
 4 just looking at the title, I think so.
 5 Q. Okay. And do you recall that
 6 what they found in that article was that 2.7%
 7 of the women in that registry had residual
 8 pain following implantation?
 9 MR. SNELL: Form.
 10 A. I'd have to see the article. I
 11 can't recall.
 12 BY MS. KIRKPATRICK:
 13 Q. Well, you'd agree with me that
 14 2.7 is significantly higher than the 1-in-500
 15 number that you've cited from your
 16 experience?
 17 A. Pain where, pain for how long?
 18 What are they talking about?
 19 Q. Okay. Well, why don't we -- we
 20 can pull that out and look through that at
 21 lunch.
 22 And the Ross article that you
 23 looked at, that was an RCT, correct?
 24 A. Yes.

24 (Pages 93 to 96)

Page 97

1 Q. Okay. And do you recall that
2 that article reported that there was 15%
3 groin pain at 12 months in the population
4 studied there?

5 A. I don't recall. I'd have to see
6 it.

7 Q. Okay. And then you also have
8 given me, from before, the Exhibit 5, which
9 is the Dr. Teo article about the "Randomized
10 trial of tension-free vaginal tape and
11 tension-free vaginal tape-obturator," do you
12 remember that?

13 A. Yes.

14 Q. And that was a randomized
15 controlled trial, correct?

16 A. Yes.

17 Q. And do you recall that 26.4% of
18 the women in that study complained of leg
19 pain after receiving the TVT-O?

20 MR. SNELL: Form.

21 A. Yes.

22 BY MS. KIRKPATRICK:

23 Q. And in fact, that the study was
24 stopped because that was such a high

Page 98

1 incidence rate of pain following the TVT-O
2 procedure?

3 MR. SNELL: Form.

4 A. I think it was short --

5 BY MS. KIRKPATRICK:

6 Q. Shortened?

7 A. Short duration of pain. I don't
8 think it was long-term pain at all. I'm not
9 sure -- really sure why they stopped that
10 study because it wasn't a severe effect.

11 Q. Okay. But of the studies that
12 you could identify for me, none of them are
13 long-term randomized control studies designed
14 specifically to look at the incidence of
15 chronic pain, are they?

16 A. I'd have to review them to be
17 able to make a comment on that.

18 Q. Okay. And do you know whether
19 any of them are long-term RCTs designed to
20 look at the rate of dyspareunia following
21 implantation of a transobturator midurethral
22 sling?

23 A. I'd have to review them.

24 Q. Okay. And do you know whether

Page 99

1 any of them are long-term RCT's designed to
2 look at the rate of groin pain after the
3 implantation of a transobturator midurethral
4 sling?

5 A. I'd have to review the studies.

6 Q. And I don't want to go through
7 all of them. Sitting here today, you just
8 don't recall one way or the other whether
9 they're long-term studies, whether they're
10 RCTs versus registries and what the primary
11 endpoint of those studies are; is that fair
12 and accurate?

13 A. I've looked at so many studies,
14 I'd have to really have them in front of me
15 to be able to make an educated comment on it.

16 Q. Okay. I don't want to give you a
17 memory test so I'm not going to ask you 10
18 questions to have you say, "I'm not sure."

19 A. Thank you.

20 Q. Let's talk about what you are
21 opining about in this case. You're not --
22 you don't offer an opinion here that a woman
23 cannot have chronic long-term pain as a
24 result of an Ethicon TVT-O mesh implant, are

Page 100

1 you?

2 A. No, I'm not.

3 Q. And you're not here to opine that
4 a woman cannot suffer from de novo
5 dyspareunia as a result of an Ethicon TVT-O
6 device, are you?

7 MR. SNELL: Form. Go ahead.

8 A. That's correct, but it's very
9 rare.

10 BY MS. KIRKPATRICK:

11 Q. Okay. But you will agree with me
12 that a TVT-O -- an Ethicon TVT-O device to
13 treat SUI can cause complications in some
14 women, correct?

15 A. Correct.

16 Q. And you'll agree with me that the
17 TVT-O device can cause groin pain?

18 A. Correct.

19 Q. And can cause chronic pain?

20 A. It can, yes.

21 Q. And it can cause acute pain?

22 A. Yes, as every surgery does.

23 Q. And can cause dyspareunia?

24 A. Yes, it can.

Christina Pramudji, M.D.

Page 101

1 Q. And it can cause vaginal pain?
2 A. I don't really see vaginal pain
3 from it.
4 Q. You don't see --
5 A. No.
6 Q. And you don't think that it can
7 cause vaginal pain?
8 A. I suppose it could.
9 Q. Okay. And you're not -- in
10 looking at Ms. Huskey's medical records and
11 in Ms. Huskey's IME and the pelvic exam you
12 did of her, you're not testifying that she is
13 not experiencing pelvic pain, correct?
14 A. That's correct.
15 Q. And in fact, the clinical
16 observations that you have made are similar
17 to the clinical observations noted by
18 Dr. Blaivas in his IME, correct?
19 A. Correct.
20 Q. And they're similar to the
21 clinical observations made by Dr. Steege in
22 his IME, correct?
23 MR. SNELL: Form.
24 A. I believe that we all found that

Page 103

1 into it, I'm going to actually ask you just a
2 couple of other general questions, hopefully
3 wrap those up again before lunch.
4 A. Okay.
5 Q. You will agree with me that a
6 medical device manufacturer has a
7 responsibility to make a safe product, don't
8 you?
9 MR. SNELL: Form.
10 A. Well, they have the
11 responsibility to make a product where the
12 benefit outweighs the risks for patients.
13 BY MS. KIRKPATRICK:
14 Q. Would that be a 51 to 49 percent,
15 or what do you mean by "outweigh"?
16 A. I mean, they can't put a number
17 on it, but you have to have good results and
18 you have to have -- there's always going to
19 be a risk with any surgery, and you could say
20 that it's not safe for any surgery because
21 that patient had a complication.
22 So you have to look at the
23 general -- the overall picture of the risks
24 and the number of risks that you see based

Page 102

1 she had tenderness specifically on the left
2 levator muscle and some tenderness throughout
3 the vagina.
4 BY MS. KIRKPATRICK:
5 Q. And so I guess what I'm getting
6 at is, your clinical observations aren't that
7 different from the clinical observations that
8 you read in the reports that were issued by
9 the plaintiff's experts in this case,
10 correct?
11 A. Correct.
12 Q. So where you differ is what the
13 cause of those injuries are.
14 A. That's right.
15 MS. KIRKPATRICK: All right. If
16 we could take a brief break, because I'd
17 like to use the ladies' room, and then
18 I'd like to look at your report and your
19 IME related to Ms. Huskey.
20 THE WITNESS: Sounds good.
21 (Recess, 11:52 a.m. to 12:10 p.m.)
22 BY MS. KIRKPATRICK:
23 Q. Instead of starting with
24 Ms. Huskey and then breaking and getting back

Page 104

1 on -- compared to the efficacy of the
2 product.
3 Q. Okay. Well, let's talk a little
4 bit about the surgical risks. Now, there is
5 a risk, I agree, associated with any surgery.
6 Correct?
7 A. Yes.
8 Q. But there's a different set of
9 risks that exists when a medical device is
10 permanently implanted in a human body,
11 correct?
12 MR. SNELL: Form.
13 A. Each surgery has its own
14 individualized risk, whether it's a medical
15 device or any kind of surgery. They have
16 their own individual risks.
17 BY MS. KIRKPATRICK:
18 Q. Well, let me see if I can make
19 this a little clearer to see if we're on the
20 same page here. For a woman who's undergoing
21 TVT surgery, TVT-O surgery, there is the
22 risks, for example, of being under general
23 anesthesia that come with any surgery,
24 correct?

26 (Pages 101 to 104)

<p style="text-align: right;">Page 105</p> <p>1 A. Correct.</p> <p>2 Q. And there's the risks of making</p> <p>3 an incision on the vaginal wall that come</p> <p>4 with any type of pelvic surgeries that are</p> <p>5 done, correct?</p> <p>6 A. That's done, yeah, with an</p> <p>7 abdominal wall incision.</p> <p>8 Q. And anywhere that you make an</p> <p>9 incision in the body, you can get a localized</p> <p>10 infection at the area of the incision,</p> <p>11 correct?</p> <p>12 A. Yes.</p> <p>13 Q. And that's the same for TVT-O</p> <p>14 surgery as it is for hernia surgery as it is</p> <p>15 for open heart surgery, correct?</p> <p>16 A. Correct.</p> <p>17 Q. So what I'm getting at is,</p> <p>18 there's certain risks that are attendant to</p> <p>19 any surgery that you perform, correct?</p> <p>20 A. Correct.</p> <p>21 Q. And then separate and apart from</p> <p>22 that, there are risks that go along with</p> <p>23 specific individual surgeries, correct?</p> <p>24 A. That's right.</p>	<p style="text-align: right;">Page 106</p> <p>1 Q. And in the case of looking at a</p> <p>2 permanently implantable medical device,</p> <p>3 there's the risks of undergoing the actual</p> <p>4 surgery at the time of surgery, correct?</p> <p>5 A. Yes.</p> <p>6 Q. And then there's the risks that</p> <p>7 you may experience because you have a</p> <p>8 permanently implantable medical device in</p> <p>9 your body, correct?</p> <p>10 MR. SNELL: Form.</p> <p>11 A. Well, there may be unique risks</p> <p>12 to that procedure. For instance, with TVT</p> <p>13 and TVT-O, the risks are the same as any</p> <p>14 pelvic surgery with the exception of mesh</p> <p>15 exposure.</p> <p>16 BY MS. KIRKPATRICK:</p> <p>17 Q. Okay. So mesh exposure is a risk</p> <p>18 that is unique to the TVT-O or, in fact, any</p> <p>19 polypropylene sling, correct?</p> <p>20 A. Correct.</p> <p>21 Q. And it's actually any kind of</p> <p>22 permanently implantable mesh into the pelvic</p> <p>23 cavity, whether it's for SUI or pelvic organ</p> <p>24 prolapse, correct?</p>
<p style="text-align: right;">Page 107</p> <p>1 A. Right.</p> <p>2 Q. So that is a unique risk. And in</p> <p>3 addition to that, when you implant a foreign</p> <p>4 body like the mesh into the pelvic cavity,</p> <p>5 you incite a foreign body reaction, correct?</p> <p>6 A. Well, even with just surgery,</p> <p>7 with sutures that are used to close the</p> <p>8 vaginal wall from any pelvic surgery, you get</p> <p>9 a foreign body reaction.</p> <p>10 Q. How often do you use</p> <p>11 polypropylene permanent sutures in the pelvic</p> <p>12 cavity?</p> <p>13 A. Well, if I do a pubovaginal</p> <p>14 sling, I would use it for that, on the ends</p> <p>15 of the sling.</p> <p>16 Q. Okay. Anything else that you use</p> <p>17 a permanently implantable polypropylene</p> <p>18 suture in the pelvic cavity?</p> <p>19 A. Well, me personally, no. I use</p> <p>20 the polypropylene mesh for the sacrocolpopexy</p> <p>21 with permanent Ethibond sutures to attach</p> <p>22 that to the vaginal wall. I know that some</p> <p>23 pelvic surgeons will do a sacrospinous</p> <p>24 ligament fixation with polypropylene sutures,</p>	<p style="text-align: right;">Page 108</p> <p>1 and those can erode.</p> <p>2 Q. And do you know of any surgery</p> <p>3 that leaves polypropylene sutures in the</p> <p>4 vagina?</p> <p>5 A. Any surgery at all?</p> <p>6 Q. Uh-huh.</p> <p>7 A. Well, sacrospinous ligament</p> <p>8 fixation, pubovaginal sling.</p> <p>9 Q. I mean in the vaginal wall</p> <p>10 itself.</p> <p>11 A. Oh, in the --</p> <p>12 Q. In the vagina, yeah, as opposed</p> <p>13 to the -- I'd asked you before about the</p> <p>14 pelvic cavity. Now I want to move on to are</p> <p>15 you aware of any surgery that is performed</p> <p>16 that would leave permanently implantable</p> <p>17 polypropylene sutures in a vagina?</p> <p>18 MR. SNELL: Form.</p> <p>19 A. I don't know.</p> <p>20 MR. SNELL: Do you mean inside</p> <p>21 the vagina or in the wall of the vagina,</p> <p>22 in the rectovaginal space behind it?</p> <p>23 What do you mean by --</p> <p>24 A. No, not in the wall of the</p>

Christina Pramudji, M.D.

Page 109

1 vagina.
 2 BY MS. KIRKPATRICK:
 3 Q. And in fact, absorbable sutures
 4 are generally used, if necessary, to close up
 5 the vaginal wall, correct?
 6 A. Correct.
 7 Q. And in fact, absorbable sutures
 8 are used in the majority of surgeries or
 9 repairs that require surgery throughout the
 10 human body, correct?
 11 MR. SNELL: Form.
 12 A. No.
 13 BY MS. KIRKPATRICK:
 14 Q. No, you don't agree with that?
 15 A. No.
 16 Q. Okay.
 17 A. Depends on the surgery that
 18 you're talking about. I mean, heart surgery
 19 they use polypropylene, cardiac surgery and
 20 vessels, they don't use absorbable sutures.
 21 Q. Okay. But you would agree with
 22 me that surgeons and physicians would default
 23 and use an absorbable suture in the first
 24 instance, and if that was not strong enough

Page 110

1 or was not for the particular application or
 2 not appropriate for that particular patient,
 3 they would then go to a polypropylene
 4 permanently implantable suture, correct?
 5 MR. SNELL: Form, foundation.
 6 A. I mean, that's a broad question.
 7 I can't -- I mean, that's a very broad
 8 question. I need more specific insight into
 9 what you're asking.
 10 BY MS. KIRKPATRICK:
 11 Q. Okay. Well, you know, I don't
 12 want to get too far afield on this. But with
 13 a pubovaginal sling, that's when you use a
 14 patient's own tissue to perform a repair for
 15 SUI, correct?
 16 A. That's correct.
 17 Q. And in that case, you do use
 18 permanent implantable polypropylene sutures,
 19 correct?
 20 A. That's correct.
 21 Q. And the actual sling itself
 22 cannot and does not erode in that surgery,
 23 correct?
 24 A. It can.

Page 111

1 Q. You've seen a woman's native
 2 tissue erode in a pubovaginal sling into an
 3 adjacent organ?
 4 A. It's been reported, yes.
 5 Q. Okay. Where has that been
 6 reported?
 7 A. I'd have to go through the
 8 papers, but there's --
 9 Q. Would it be in the materials that
 10 you've provided to me?
 11 A. Yes.
 12 Q. If that has been reported in the
 13 medical literature, you would have noted that
 14 here?
 15 A. Yes.
 16 Q. And it's the actual sling
 17 material itself as opposed to the
 18 polypropylene sutures that you believe can
 19 erode into an adjacent organ?
 20 A. It can, yes.
 21 Q. Have you ever seen it?
 22 A. I've never seen it, no.
 23 Q. Okay. Have you ever used
 24 polypropylene slings in the bladder --

Page 112

1 MR. SNELL: Form.
 2 BY MS. KIRKPATRICK:
 3 Q. -- for any kind of bladder
 4 surgery? I'm sorry, suture, polypropylene
 5 suture in the bladder.
 6 A. Okay.
 7 MR. SNELL: Form.
 8 BY MS. KIRKPATRICK:
 9 Q. No wonder you were looking at me
 10 like I was crazy.
 11 A. Yeah.
 12 Q. I was curious, where is she
 13 getting that?
 14 A. No.
 15 Q. Okay. Why not?
 16 A. We use absorbable suture in that.
 17 Absorbable suture is adequate for that
 18 application.
 19 Q. Okay. And actually, using the
 20 absorbable suture in the bladder application,
 21 it eliminates the risk of potential erosion,
 22 correct?
 23 A. Decreases the risk.
 24 Q. Have you ever seen an absorbable

28 (Pages 109 to 112)

<p style="text-align: right;">Page 113</p> <p>1 suture erode?</p> <p>2 A. No, I have not.</p> <p>3 Q. Have you ever seen that reported</p> <p>4 in the medical literature?</p> <p>5 A. I don't think so.</p> <p>6 Q. Okay. What I'm getting at is in</p> <p>7 these applications, it's the polypropylene</p> <p>8 suture that erodes as opposed to the</p> <p>9 absorbable suture or the native tissue.</p> <p>10 MR. SNELL: Form.</p> <p>11 A. Yeah. I mean, a permanent</p> <p>12 structure is going to have potentially more</p> <p>13 likelihood than an absorbable suture because</p> <p>14 it's there longer.</p> <p>15 BY MS. KIRKPATRICK:</p> <p>16 Q. And you'll agree with me that the</p> <p>17 amount of polypropylene used in a midurethral</p> <p>18 sling greatly exceeds the amount of</p> <p>19 polypropylene that's used in the sutures used</p> <p>20 to secure a pubovaginal sling, correct?</p> <p>21 A. It is more polypropylene, yes.</p> <p>22 Q. And it's a lot more</p> <p>23 polypropylene?</p> <p>24 MR. SNELL: Form.</p>	<p style="text-align: right;">Page 114</p> <p>1 A. Well, it's a 1-centimeter mesh</p> <p>2 tape that's used.</p> <p>3 BY MS. KIRKPATRICK:</p> <p>4 Q. Okay. And it's a 1-centimeter</p> <p>5 mesh tape that's made out of single-filament</p> <p>6 polypropylene, correct?</p> <p>7 A. Correct.</p> <p>8 Q. And the suture itself is just a</p> <p>9 single filament of polypropylene, right?</p> <p>10 A. Correct.</p> <p>11 Q. That's used to close up a small</p> <p>12 hole, correct?</p> <p>13 A. Right.</p> <p>14 Q. About how much polypropylene --</p> <p>15 single filament of polypropylene do you use</p> <p>16 in a suture?</p> <p>17 MR. SNELL: Form.</p> <p>18 A. Can you restate that?</p> <p>19 BY MS. KIRKPATRICK:</p> <p>20 Q. How long is it? Is it</p> <p>21 a centimeter, 2 centimeters, 3 centimeters,</p> <p>22 4?</p> <p>23 MR. SNELL: Form.</p> <p>24 A. What application are you talking</p>
<p style="text-align: right;">Page 115</p> <p>1 about?</p> <p>2 BY MS. KIRKPATRICK:</p> <p>3 Q. In a pubovaginal sling.</p> <p>4 A. Pubovaginal sling, it would be</p> <p>5 about 10 centimeters.</p> <p>6 Q. So you use 10 centimeters total</p> <p>7 of a single-filament --</p> <p>8 A. 10 centimeters on each side.</p> <p>9 Q. Okay. So 20 centimeters, thank</p> <p>10 you, so that's total.</p> <p>11 Okay. So we had talked a little</p> <p>12 bit before about your experience in removing</p> <p>13 retropubic slings. Do you remember that?</p> <p>14 A. Yes.</p> <p>15 Q. And you told me that you had</p> <p>16 removed about 300 -- I'm sorry. You had</p> <p>17 implanted about 300 total and you had removed</p> <p>18 1 to 2 and you had, just on a repair, of</p> <p>19 about 1 to 2. Is that right?</p> <p>20 A. Correct.</p> <p>21 Q. I forgot to ask you how many</p> <p>22 transobturator slings you've implanted.</p> <p>23 A. About 700.</p> <p>24 Q. And do you still use the Ethicon</p>	<p style="text-align: right;">Page 116</p> <p>1 TVT-O?</p> <p>2 A. Yes.</p> <p>3 Q. And how many TVT-O's have you</p> <p>4 removed?</p> <p>5 A. One.</p> <p>6 Q. And how many have you --</p> <p>7 A. It's very unusual.</p> <p>8 Q. -- gone in to do a revision on?</p> <p>9 A. For mesh exposure, for</p> <p>10 obstruction? What are you referring to?</p> <p>11 Q. You were the one who made the</p> <p>12 distinction that there was a difference</p> <p>13 between doing a removal surgery and then</p> <p>14 doing what you consider to be a less invasive</p> <p>15 revision surgery. So you've done one of the</p> <p>16 more invasive removal surgeries and I'm</p> <p>17 trying to figure out how many of the less</p> <p>18 invasive revision surgeries you have done.</p> <p>19 A. I don't have a number at the top</p> <p>20 of my head, but it's, you know, maybe out of</p> <p>21 700, there may be 20 that I had to go in and</p> <p>22 cut the sling or go back for a mesh exposure</p> <p>23 somewhere, ballpark that number, and that</p> <p>24 would include my patients and patients that</p>

Christina Pramudji, M.D.

Page 117

1 were referred to me.
2 Q. Okay. And you would agree with
3 me, though, with the transobturator slings,
4 you can't completely remove it if something
5 goes wrong. Is that right?
6 A. It can be completely removed.
7 Q. You think you can remove it
8 without damaging a woman's pelvic anatomy?
9 A. Well, you have to dissect through
10 the muscles and it's very difficult and it's
11 very rarely done, but it can be completely
12 removed. And damaging -- I mean, it depends
13 on how you define that. You -- you know, you
14 do have to go through muscle, so we don't do
15 it very often. It's kind of painful to
16 recover from.
17 Q. What muscles do you have to go
18 through in a removal surgery?
19 A. It's the muscles of the obturator
20 foramen.
21 Q. Anything else?
22 A. No.
23 Q. Okay. And you know that
24 Ms. Huskey had to have her sling partially

Page 119

1 complications.
2 Can you give me the kind of
3 laundry list of complications that you would
4 routinely tell all of your patients are
5 potential complications from a TVT-O?
6 A. Well, in --
7 Q. And when I say TVT-O, I mean any
8 transobturator midurethral polypropylene
9 sling.
10 A. So in general, I will tell them
11 about the risk of bleeding, infection, injury
12 to the bladder or the urethra, groin pain,
13 which is typically transitory, failure of the
14 wound to heal with mesh exposure and need for
15 further surgery to repair that, pain, chronic
16 pain, dyspareunia, de novo urge incontinence,
17 persistent urge incontinence, urinary
18 retention, temporary or permanent, requiring
19 sling release, potential sling removal.
20 Q. And for each of those, you think
21 that is important information to provide to a
22 woman so she can make an informed decision as
23 to whether she's willing to accept the risks
24 of the implantation of a TVT-O sling,

Page 118

1 removed. Is that right?
2 A. It was partially removed, yes.
3 Q. Okay. And when it was partially
4 removed, you are aware that her physician
5 reported that some of the sling retracted
6 back behind the pubic bone. Is that right?
7 MR. SNELL: Form.
8 Go ahead.
9 A. Well, he was pulling on it to try
10 to dissect it as far as he could, so he was
11 putting tension on it whenever he cut it, so
12 I would expect it to retract, just like any
13 tissue would.
14 BY MS. KIRKPATRICK:
15 Q. Okay. But at least you'll agree
16 with me it's certainly not easy to fully
17 remove a transobturator sling if a
18 complication arises, correct?
19 A. That's correct.
20 Q. We had also started to talk about
21 some of the warnings that you gave to your
22 own patients who receive the TVT-O, and I had
23 asked you about what warnings you
24 particularly tell your patients of potential

Page 120

1 correct?
2 A. Most women, yes. And some are
3 more important to some women than to others.
4 Q. Okay. Are there any of these
5 that you think are particularly important to
6 thin, active women?
7 MR. SNELL: Form.
8 A. I think they're all important to
9 thin, active women.
10 BY MS. KIRKPATRICK:
11 Q. Okay. Are there any other --
12 correct me if I'm wrong on this, but I think
13 you also said that there are sometimes
14 warnings that you give patients that might be
15 unique to their particular circumstances or
16 medical conditions.
17 Are there any particular medical
18 conditions or circumstances that you can
19 think of that would warrant different
20 additional warnings regarding the
21 implantation of a TVT-O or a transobturator
22 midurethral sling?
23 MR. SNELL: Form.
24 A. Well, if a patient is sexually

30 (Pages 117 to 120)

<p style="text-align: right;">Page 121</p> <p>1 active, then I would warn her about the risk 2 of dyspareunia with any pelvic surgery. But 3 if it's an older patient that's not sexually 4 active, then it's not -- you know, it's not 5 as important. 6 For a patient with mixed 7 incontinence, with urge incontinence, I would 8 focus on the risk of persistent urge 9 incontinence. 10 For a patient with poor bladder 11 emptying or a difficulty emptying her 12 bladder, I would warn her of the risk of 13 retention, which might be increased for that 14 patient. 15 And if a patient has thin 16 tissues, atrophy or radiation, we would have 17 a discussion about that, about the risk of 18 not being able to heal as well, or if she's a 19 smoker, chronic smoker, we would have a 20 discussion about that so that she could make 21 an informed decision. 22 BY MS. KIRKPATRICK: 23 Q. Okay. 24 A. And I might start a patient with</p>	<p style="text-align: right;">Page 122</p> <p>1 atrophy on estrogen ahead of time, if it's 2 medically warranted. 3 Q. Okay. And atrophy is something 4 that happens in a significant population of 5 menopausal women, correct? 6 A. Yes. 7 Q. And you would expect to see some 8 change in or thinning of their vaginal tissue 9 with menopause, correct? 10 A. Yes. 11 Q. Do you tell all of -- and, you 12 know, barring some godforsaken circumstance, 13 most women hope that they make it until 14 they're old enough to be in menopause, 15 correct? 16 A. Yes. 17 Q. And you would just assume that 18 most of your patients who are coming in are 19 likely to get to the point of menopause if 20 they're not already there, right? 21 A. Correct. 22 Q. Do you tell any of your patients 23 about the risks that may be attendant to 24 menopausal changes in their vaginal structure</p>
<p style="text-align: right;">Page 123</p> <p>1 and the implantation of a TVT-O device? 2 A. I don't think that's really been 3 borne out in the long-term literature, the 4 17-year data going out on TVT with, you know, 5 exposure suddenly occurring or erosions 6 occurring. 7 So that's part of the discussion 8 with the mesh exposure, a need for further 9 surgery down the line, but I don't 10 specifically talk about that because I don't 11 think that's really been borne out in the 12 vast experience that we have with TVT and 13 TVT-O. 14 Q. Okay. Now, just talking about 15 pain just for a couple of minutes, there's 16 different kinds of pain that anyone can 17 experience, correct? 18 A. Correct. 19 Q. And I'd like to use the example, 20 you can have the regular headache that you've 21 got to take a couple of Advil for, right, and 22 that's different from the pain you experience 23 with a migraine, correct? 24 A. Correct.</p>	<p style="text-align: right;">Page 124</p> <p>1 Q. Or the pain that you might 2 experience with a concussion, correct? 3 A. Yes. 4 Q. Even though they all fall under 5 the kind of umbrella of being a headache. 6 A. Correct. 7 Q. And that also is borne out with 8 pelvic pain, correct? 9 A. Yes. 10 Q. And there's different kinds of 11 pelvic pain that women can experience? 12 A. Yes, there's all kinds of 13 different types of pelvic pain. 14 Q. And there's pelvic pain, for 15 example, that women can experience with 16 menstrual cramps? 17 A. Yes. 18 Q. And there's pelvic pain that you 19 can experience if you have a vaginal 20 infection or a yeast infection or something 21 like that? 22 A. Right. 23 Q. And there's pelvic pain that you 24 can have from having a bladder infection or</p>

Christina Pramudji, M.D.

Page 125

1 something like that, correct?
2 A. (Witness nods head.)
3 Q. And do you find in your practice
4 that many women are able to, for example,
5 distinguish between the pain of a bladder
6 infection and menstrual cramps, for example?
7 A. Yes.
8 Q. And women generally can
9 differentiate between the degree of pain that
10 they're experiencing pelvically?
11 MR. SNELL: Form.
12 Go ahead.
13 A. Most of the time, but there is a
14 lot of overlap in the pelvic area so
15 sometimes it's very difficult to pinpoint
16 where the pain is coming from.
17 BY MS. KIRKPATRICK:
18 Q. Okay. And the same is also true
19 that there's different types of dyspareunia
20 and pain with sex, correct?
21 A. Yes.
22 Q. And so there's dyspareunia that
23 can be caused by vaginal dryness that's
24 brought on by menopause, correct?

Page 127

1 they're experiencing, correct?
2 A. Yes.
3 Q. Okay. And infection is the same;
4 there can be an acute infection at a surgical
5 site, correct?
6 A. Yes.
7 Q. And that's resolved in one
8 particular way, correct?
9 A. Yes.
10 Q. And then there can also be
11 chronic infections, correct, and those differ
12 from the acute infection?
13 A. Yes, sometimes.
14 Q. Okay. And they're treated
15 differently --
16 MR. SNELL: Form.
17 BY MS. KIRKPATRICK:
18 Q. -- than an acute infection?
19 A. Usually still treated with
20 antibiotics, if it's a bacterial infection,
21 yes.
22 Q. But it may be the difference
23 between applying, for example, an antibiotic
24 ointment to the site of a surgical incision

Page 126

1 A. Yes.
2 Q. And that's different than the
3 dyspareunia or painful sex that someone can
4 have following, for example, a hysterectomy,
5 when there's some kind of scarring at the
6 vaginal apex, correct?
7 A. Yes.
8 Q. And all of that's different from
9 the type of dyspareunia that you would
10 experience if you have a point of tenderness
11 on your vaginal wall in some way, correct?
12 MR. SNELL: Form.
13 A. Probably, yes.
14 BY MS. KIRKPATRICK:
15 Q. Okay. So dyspareunia isn't
16 dyspareunia isn't dyspareunia, correct?
17 A. Right.
18 Q. And you feel that it's important
19 to look at each patient individually to look
20 at their specific symptoms and their specific
21 circumstances to distinguish what type of
22 pelvic pain they're having, correct?
23 A. Ideally, yes.
24 Q. Or what type of dyspareunia

Page 128

1 on your skin versus oral antibiotics versus
2 IV antibiotics, correct?
3 MR. SNELL: Form.
4 A. It's hard to just categorize it
5 that acute you do this and chronic you do
6 this, because it's --
7 BY MS. KIRKPATRICK:
8 Q. Okay. Fair enough. Fair enough.
9 But you'll agree with me that
10 those are different types of infections and
11 they can't all be lumped together, because
12 they have to be examined and treated
13 differently as to what their particular
14 source is and what the particular duration
15 is, correct?
16 MR. SNELL: Form.
17 Go ahead.
18 A. Yeah, you have to take the
19 patient's current situation into
20 consideration, what kind of organism you
21 have, the patient's symptoms, how sick they
22 are; that all has to be taken into
23 consideration.
24 BY MS. KIRKPATRICK:

32 (Pages 125 to 128)

Christina Pramudji, M.D.

Page 129

1 Q. Okay. And there's also
2 subclinical infections that can exist in the
3 body as well, correct?
4 A. Yes.
5 Q. Okay. Now, you've testified
6 earlier that it takes about 10 minutes to do
7 a TVT-O surgery. Is that right?
8 A. Correct.
9 Q. And how long is it for a woman
10 from the time she is, you know, wheeled into
11 the operating room till when she comes out of
12 anesthesia?
13 MR. SNELL: Form.
14 A. Till she comes out of the
15 operating room or wakes up in recovery room?
16 BY MS. KIRKPATRICK:
17 Q. Wakes up in the recovery room.
18 A. So --
19 MR. SNELL: Hold on. Same
20 objection.
21 Go ahead.
22 A. Probably about an hour and a
23 half, hour and 45 minutes.
24 BY MS. KIRKPATRICK:

Page 131

1 A. The prep takes a little longer,
2 so it's probably about two and a half hours.
3 Q. Okay. So we're tacking an extra
4 maybe 45 minutes on to the total time?
5 A. Yes.
6 Q. Okay. Now, removal surgeries.
7 The surgery that you did to remove the TVT-O,
8 how long did that take?
9 A. About 20, 30 minutes.
10 Q. Okay. And is that about the same
11 amount of time under -- from the beginning to
12 coming out of general anesthesia as the TVT-O
13 procedure itself?
14 A. Yes.
15 Q. About an hour? You know from
16 talking to your colleagues that some of their
17 removal surgeries can be significantly longer
18 than that, correct?
19 A. Yeah. I've read even in some of
20 the records that they take longer to do it.
21 Q. Do you remember how long
22 Ms. Huskey's took?
23 A. I don't remember.
24 Q. And you will agree with me that

Page 130

1 Q. Okay. So she's under general
2 anesthesia for about one hour and 45 minutes
3 with a TVT-O procedure?
4 A. No, she's under a general
5 anesthetic about 20 or 30 minutes.
6 Q. Okay, 20 to 30 minutes, okay,
7 you're right. So it's about an hour and 45
8 minutes from start until when she wakes up
9 and about 30 -- 20 to 30 minutes of that
10 she's under general anesthesia?
11 A. Correct, and the rest she would
12 be in the recovery room just kind of coming
13 out, you know, breathing on her own, not
14 being administered more anesthesia.
15 Q. Okay. How long does it take you
16 to perform a pubovaginal sling surgery?
17 A. 45 minutes.
18 Q. So it's a difference of about 35
19 minutes of actual surgery time?
20 A. Uh-huh.
21 Q. How long is it from the start
22 when she's wheeled into the operating room
23 till a woman comes out of anesthesia with a
24 pubovaginal sling?

Page 132

1 the removal surgeries can be significantly
2 more complicated than the original
3 implantation surgery for the TVT-O, right?
4 MR. SNELL: Form.
5 A. It can be harder to find the
6 sling if it's not a dyed sling.
7 BY MS. KIRKPATRICK:
8 Q. And the removal surgery requires
9 dissection of some of the pelvic tissue,
10 correct?
11 A. Well, it requires dissecting
12 around the urethra, primarily.
13 Q. And that can cause additional
14 scar tissue, correct, simply because you're
15 having more surgery in the same location?
16 A. It could, yes.
17 Q. Are there any other complications
18 that you think are risks that come from the
19 removal surgery itself?
20 A. No.
21 Q. So just the possibility of
22 additional scarring?
23 A. Yes.
24 Q. Okay. We've been talking a lot

33 (Pages 129 to 132)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 133</p> <p>1 about kind of the procedure that's used here. 2 You're not a biomaterials expert, correct? 3 A. Well, I know about the materials 4 that I use for surgery, so I would say that 5 I -- you know, I'm knowledgeable about what I 6 implant in patients. 7 Q. Okay. What's the Ethicon TVT-O 8 sling made of? 9 A. Polypropylene. 10 Q. Okay. What's added to that 11 polypropylene? 12 A. What's added to it? 13 Q. Uh-huh. 14 A. I don't know if anything's added 15 to it. 16 Q. Do you know if there's any 17 antioxidants used in it? 18 A. No, I don't know. 19 Q. Do you know what its molecular 20 weight is? 21 A. I've seen it before, but I don't 22 know off the top of my head. 23 Q. Do you know whether it's been 24 oxidized before it's been placed into a</p>	<p style="text-align: right;">Page 134</p> <p>1 woman's body? 2 A. No. 3 Q. Do you know anything about the 4 process of oxidation of polypropylene? 5 A. No. 6 Q. And that's not the type of 7 information -- you know that it's made of 8 polypropylene, but you're not intending to 9 offer opinions here concerning the chemical 10 processes that are involved with 11 polypropylene, correct? 12 A. I don't know about the chemical 13 processes. 14 Q. Okay. So you would defer -- you 15 would defer to other experts who would be 16 biomaterials experts or who would be 17 specialists in polypropylene for that 18 particular type of information? 19 MR. SNELL: Form. 20 A. I know how it -- I focus on it 21 from the perspective of my patients. 22 BY MS. KIRKPATRICK: 23 Q. Okay. So you focus, though, on 24 how you believe the polypropylene sling</p>
<p style="text-align: right;">Page 135</p> <p>1 performs in your patients, both from an 2 efficacy standpoint, correct, and from 3 complications that you see? 4 A. From my experience and from the 5 vast body of literature that's available on 6 polypropylene slings. 7 Q. Okay. But I guess I'm just 8 trying to figure out what the parameters of 9 your testimony are. You're not going to come 10 in and you're not planning on holding 11 yourself out as an expert on polymers and 12 polypropylene and degradation or any of those 13 particular issues related to polypropylene, 14 are you? 15 MR. SNELL: Form. And I will say 16 she is. I am putting her up on that, and 17 it is in her report. 18 BY MS. KIRKPATRICK: 19 Q. Okay. How does polypropylene 20 degrade? 21 A. It doesn't degrade. 22 Q. So your opinion, sitting here 23 today, that there is no way that any 24 polypropylene that exists in this world can</p>	<p style="text-align: right;">Page 136</p> <p>1 degrade? 2 MR. SNELL: That's overbroad, 3 form. 4 Go ahead. 5 A. That's a very broad question. 6 You know, from how it's used in the body in 7 sutures and in slings, it doesn't degrade; 8 that's why it's a permanent suture. That's 9 why heart surgeons rely on it and cardiac 10 surgeons rely on it to sew up your aorta when 11 you have aortic surgery. 12 So if it degraded, it would not 13 be used in that application. There's no 14 clinical degradation that occurs. 15 BY MS. KIRKPATRICK: 16 Q. So you believe that there's no 17 evidence that exists, either in Ethicon's own 18 documents or in the literature, that supports 19 the theory that polypropylene sutures can 20 degrade -- 21 MR. SNELL: Form. 22 Go ahead. 23 BY MS. KIRKPATRICK: 24 Q. -- in vivo?</p>

34 (Pages 133 to 136)

Christina Pramudji, M.D.

Page 137

1 MR. SNELL: Form.

2 A. I mean, I can't say that there's
3 nothing out there that they didn't do any
4 kind of manipulation to polypropylene or look
5 at it a certain way and found some
6 degradation there, but does it matter to
7 patients and to this case, no.

8 BY MS. KIRKPATRICK:

9 Q. Has Mr. Snell or any of the
10 attorneys for Ethicon provided you with any
11 Ethicon documents reflecting degradation of
12 polypropylene sutures?

13 A. I mean, I think I saw some
14 internal communication, I can't remember if
15 it was from Mr. Kountze or from Mr. Snell, I
16 don't remember, but I know that that is out
17 there, that that was something that the
18 engineers were talking about and Ethicon was
19 talking about.

20 But clinically, I'm telling you
21 it does not make a difference, and I don't
22 believe that there's degradation that occurs
23 that it makes any hill of beans' difference
24 for patients.

Page 139

1 Q. And don't you think that the
2 information that Ethicon has and the
3 knowledge that Ethicon has concerning the
4 degradation of polypropylene sutures would be
5 something that you would want to see in
6 reaching your opinions concerning the
7 degradation of polypropylene sutures?

8 MR. SNELL: Form.

9 A. No.

10 BY MS. KIRKPATRICK:

11 Q. You don't think it's important
12 what your -- what Ethicon has said about its
13 own sutures for you to reach your conclusion.
14 Is that right?

15 A. Right.

16 Q. Okay. Have you ever tested it to
17 see whether it degrades?

18 A. No.

19 Q. Have you ever looked at
20 polypropylene under a microscope?

21 A. I've seen pictures of it under a
22 microscope.

23 Q. Have you looked at it yourself?

24 A. No.

Page 138

1 Q. Okay. So let me just figure out
2 what you are testifying about and what you're
3 not testifying about. You don't have a basis
4 for saying whether polypropylene does or
5 doesn't degrade.

6 What you are here to offer your
7 opinion on is that regardless of whether
8 polypropylene degrades or doesn't degrade,
9 there's no clinical significance to a
10 particular patient?

11 A. I don't think it degrades.

12 MR. SNELL: Hold on, hold on,
13 hold on. Form. That misstates, too.
14 Go ahead.

15 A. I don't think it degrades and I
16 think there's other evidence that shows that
17 it doesn't degrade.

18 BY MS. KIRKPATRICK:

19 Q. Have you asked Ethicon, in
20 reaching that opinion, to provide you with
21 all of the information that they have
22 concerning the potential degradation of
23 polypropylene sutures?

24 A. No.

Page 140

1 Q. Have you ever looked at explanted
2 polypropylene sutures and analyzed them to
3 see whether there's any degradation in them?

4 A. No, I have not.

5 Q. Have you ever looked at explanted
6 polypropylene mesh to see if there's any
7 degradation in that mesh?

8 A. I've looked at -- when I've taken
9 it out of patients, I've looked at it and
10 it's intact.

11 Q. Okay. Let me just clarify. Have
12 you ever looked at it microscopically to see
13 whether it has degraded microscopically?

14 A. I've looked at the images that
15 the pathologists have provided to me because
16 I get images back from them.

17 Q. Okay. How many of those images
18 have you looked at?

19 A. I don't know, 10, 20.

20 Q. Have you ever asked a pathologist
21 to see whether the polypropylene had
22 deteriorated?

23 A. No.

24 Q. That's not something that you

35 (Pages 137 to 140)

Christina Pramudji, M.D.

Page 141

1 standardly do when you remove polypropylene
2 from a woman?

3 A. No, because it doesn't
4 deteriorate.

5 Q. How do you know that?

6 MR. SNELL: Form, asked and
7 answered.

8 A. Because it doesn't. It's a
9 permanent suture. You can go back in 20
10 years and you'll still find it in there.

11 BY MS. KIRKPATRICK:

12 Q. And so your -- is it your opinion
13 here that because 20 years from now, you can
14 find a polypropylene suture where you
15 implanted it and it has not completely
16 disappeared, therefore it cannot degrade?

17 MR. SNELL: Form.

18 A. 20, 30, 40 years, it's going to
19 be there. It's not degrading.

20 BY MS. KIRKPATRICK:

21 Q. Do you think it can crack?

22 A. No.

23 Q. Do you think that it can release
24 particles from the surface?

Page 143

1 removed, you don't visibly see deterioration?

2 MR. SNELL: Form.

3 A. That's part of it, but also
4 because polypropylene is relied upon by
5 surgeons throughout the world for the last 40
6 years as a permanent suture. If we were
7 having aortas busting open after 30 years, we
8 wouldn't be relying on it.

9 BY MS. KIRKPATRICK:

10 Q. So that's the basis for your
11 opinion here, it's not any independent study
12 that you've done, correct?

13 MR. SNELL: Form.

14 A. In looking at the literature as
15 well. It's not reported as degrading.

16 BY MS. KIRKPATRICK:

17 Q. You've never seen any literature
18 that reports polypropylene degrading?

19 A. Not any significant good
20 literature. Some remote studies.

21 Q. Okay. What literature have you
22 been provided with by Ethicon regarding
23 degradation? What articles have you looked
24 at?

Page 142

1 A. No.

2 Q. Do you think that it changes its
3 chemical composition in any way at all?

4 A. No.

5 Q. Do you think that polypropylene
6 used in the body can change its molecular
7 weight?

8 A. No.

9 Q. Do you think that polypropylene
10 that is used in the body can undergo any
11 mechanical changes to it?

12 MR. SNELL: Form.

13 A. Depending on where it's placed
14 and what happens with that patient, it could
15 move slightly, because it's -- you know, just
16 the position of it, like a hernia repair, if
17 a patient gained a lot of weight, it could
18 change its position slightly, if that's what
19 you're referring to. But it doesn't just
20 change on its own.

21 BY MS. KIRKPATRICK:

22 Q. Okay. And once again, the basis
23 for your opinion on that is when you have
24 looked at the polypropylene that you've

Page 144

1 A. I can't recall right now.

2 Q. Okay. And when you say not any
3 good literature, what literature are you
4 referring to that would be -- I don't want to
5 say bad literature just because it's the
6 opposite of good -- that documents or deals
7 with degradation of polypropylene in the
8 body?

9 A. I mean, I think there was maybe a
10 polymer article or something like that that
11 was talking about it in some journal, but I
12 can't recall. But nothing in the major body
13 of literature that has brought that up as an
14 issue. It's just not an issue.

15 Q. You don't believe that that's an
16 issue at all?

17 A. No.

18 Q. And you don't believe that that's
19 an issue that's been addressed in the medical
20 and scientific literature?

21 A. No.

22 Q. And it's not an issue that was
23 addressed in the materials that were provided
24 to you by Ethicon, either from their internal

36 (Pages 141 to 144)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 145</p> <p>1 documents or from the literature that they</p> <p>2 provided you with, correct?</p> <p>3 MR. SNELL: Form.</p> <p>4 A. Correct.</p> <p>5 BY MS. KIRKPATRICK:</p> <p>6 Q. Okay. And you haven't done</p> <p>7 any -- you don't have any specialized</p> <p>8 training in polymer chemistry, do you?</p> <p>9 MR. SNELL: Form.</p> <p>10 A. Well, I'm a chemical engineer, so</p> <p>11 I had some training in polymers and</p> <p>12 chemistry.</p> <p>13 BY MS. KIRKPATRICK</p> <p>14 Q. Okay.</p> <p>15 A. But, you know -- and that was a</p> <p>16 long time ago. But, I mean, my main concern</p> <p>17 is with patients, you know, the materials</p> <p>18 that I put in patients and how they -- what</p> <p>19 the literature bears out and how they respond</p> <p>20 to it.</p> <p>21 BY MS. KIRKPATRICK:</p> <p>22 Q. So when you take a TVT-O or any</p> <p>23 kind of midurethral sling out of a patient,</p> <p>24 does it look exactly the same as it did when</p>	<p style="text-align: right;">Page 146</p> <p>1 it went in?</p> <p>2 A. Sometimes it does, yeah.</p> <p>3 Q. Okay. And when -- how often is</p> <p>4 that?</p> <p>5 A. Most of the time.</p> <p>6 Q. Most of the time --</p> <p>7 A. Yeah.</p> <p>8 Q. -- you take out a soft, pliable,</p> <p>9 pristine --</p> <p>10 A. It's this -- yeah, and it's the</p> <p>11 same strip but it has the ingrowth of tissue</p> <p>12 in it. But other than that, typically it's</p> <p>13 just laying, you know -- laying nice and</p> <p>14 flat. It does not look degraded or deformed</p> <p>15 or rolled or curled or twisted or anything.</p> <p>16 Q. Would you feel differently if you</p> <p>17 learned or saw evidence that the resin used</p> <p>18 in Ethicon meshes have additives that weren't</p> <p>19 supposed to be used in the human body?</p> <p>20 MR. SNELL: Form, foundation.</p> <p>21 A. No, because it's been proven in</p> <p>22 millions of women that it's not a problem.</p> <p>23 BY MS. KIRKPATRICK:</p> <p>24 Q. So you wouldn't be interested in</p>
<p style="text-align: right;">Page 147</p> <p>1 that information?</p> <p>2 A. No.</p> <p>3 Q. Okay. And if you learned that</p> <p>4 Ethicon meshes had additives that weren't</p> <p>5 supposed to be used in the human body, you</p> <p>6 don't think that that's something that a</p> <p>7 woman, in making a TVT -- a decision to have</p> <p>8 a TVT-O, would have the right to know?</p> <p>9 MR. SNELL: Form, foundation.</p> <p>10 A. No, I don't think it's -- I don't</p> <p>11 think it's pertinent.</p> <p>12 BY MS. KIRKPATRICK:</p> <p>13 Q. And you don't think it's</p> <p>14 pertinent and you don't think that a woman</p> <p>15 has the right to know that?</p> <p>16 MR. SNELL: Same objection, form</p> <p>17 and foundation. Asked and answered.</p> <p>18 A. Do you want me to answer that</p> <p>19 again?</p> <p>20 BY MS. KIRKPATRICK:</p> <p>21 Q. Please.</p> <p>22 A. Okay. No, I don't think so.</p> <p>23 Q. Okay. And there's nothing that</p> <p>24 you could learn or you would want to know</p>	<p style="text-align: right;">Page 148</p> <p>1 about the specific material used in a TVT --</p> <p>2 an Ethicon TVT or TVT-O product that would</p> <p>3 change your opinion, is there?</p> <p>4 A. Can you repeat that question?</p> <p>5 Q. Probably not. I'm going to</p> <p>6 reread it. I don't think I can do that.</p> <p>7 There's nothing that you could</p> <p>8 learn or you would want to know about the</p> <p>9 specific material used in an Ethicon TVT or</p> <p>10 TVT-O product that would change your opinion</p> <p>11 on this topic, is there?</p> <p>12 MR. SNELL: Form.</p> <p>13 A. No.</p> <p>14 BY MS. KIRKPATRICK:</p> <p>15 Q. Okay. And there's nothing that</p> <p>16 you could see in the medical literature about</p> <p>17 degradation of polypropylene that would</p> <p>18 change your opinion on this matter?</p> <p>19 A. No, because it's not going to</p> <p>20 outweigh all the other literature and all my</p> <p>21 experience.</p> <p>22 Q. Okay. Why don't we take a break</p> <p>23 for lunch.</p> <p>24 MR. SNELL: That sounds good.</p>

37 (Pages 145 to 148)

Christina Pramudji, M.D.

Page 149

1 (Recess, 12:50 p.m. to 1:49 p.m.)
2 BY MS. KIRKPATRICK:
3 Q. Okay. I want to turn to the
4 instructions for use.
5 A. Okay.
6 Q. And I believe we'll mark this as
7 Exhibit 9.
8 (Whereupon, Exhibit Pramudji-9,
9 Gynecare TVT Obturator System
10 Instructions for Use, was marked for
11 identification.)
12 BY MS. KIRKPATRICK:
13 Q. And you've seen that before,
14 Dr. Pramudji, haven't you?
15 A. Yes.
16 Q. And this was actually something
17 that the lawyers for Ethicon had given you in
18 connection with your testimony. Is that
19 right?
20 A. Yes.
21 MR. SNELL: Objection, form.
22 BY MS. KIRKPATRICK:
23 Q. I'd like you to look at the last
24 two pages here.

Page 151

1 And you will agree with me that
2 not every woman's pelvis is identical to the
3 next woman, correct?
4 A. Correct.
5 Q. And that the placement of nerves,
6 particularly the peripheral branches of
7 nerves, can differ from patient to patient,
8 correct?
9 A. Correct.
10 Q. And even the placement of the
11 vessels can be, you know, a little bit
12 different from patient to patient, correct?
13 A. Correct.
14 Q. And there's a difference in how
15 you do surgery on women who are obese,
16 correct?
17 MR. SNELL: Form.
18 A. There may be slight adjustments
19 that you would make, but it's generally the
20 same.
21 BY MS. KIRKPATRICK:
22 Q. Okay. So you would take into
23 account if a woman was obese --
24 A. Yes.

Page 150

1 A. Okay.
2 Q. And you'll see under the warnings
3 and precautions, it says not to use the TVT-O
4 for patients who are in anticoagulation
5 therapy. That doesn't apply to Ms. Huskey,
6 does it?
7 A. Correct.
8 Q. And she didn't have a urinary
9 tract infection at the time that you could
10 see in the records, correct?
11 A. Correct.
12 Q. Was there anything else about
13 Ms. Huskey that in your opinion made her not
14 an appropriate candidate for the implantation
15 of the TVT-O --
16 A. No.
17 Q. -- sling?
18 A. No.
19 Q. Okay. It also says here that
20 "The Gynecare TVT Obturator procedure should
21 be performed with care to avoid large
22 vessels, nerves, bladder and bowel.
23 Attention to patient anatomy and correct
24 passage of the device will minimize risks."

Page 152

1 Q. -- and that's different than
2 things you may take into account if a woman
3 is thin --
4 A. Correct.
5 Q. -- or of a normal weight?
6 A. Yes.
7 Q. Okay. Now, you'll see here it
8 says, "Do not perform this procedure if you
9 think the surgical site may be infected or
10 contaminated." Do you see that here?
11 A. Yes.
12 Q. Okay. Now, the surgical site is
13 in the vaginal wall, correct?
14 A. Yes.
15 Q. And the vagina, you'll agree with
16 me, is a contaminated space?
17 A. It is. Clean -- we consider it
18 clean-contaminated after the prep.
19 Q. Clean-contaminated, but it's
20 still contaminated, correct?
21 A. Correct.
22 Q. And there's still bacteria,
23 naturally occurring flora in the vagina, even
24 after it's clean-contaminated and prepped for

38 (Pages 149 to 152)

<p style="text-align: right;">Page 153</p> <p>1 surgery, correct?</p> <p>2 A. Yes.</p> <p>3 Q. So can you explain this to me,</p> <p>4 how -- it sounds to me like Ethicon is</p> <p>5 recommending that you don't perform this</p> <p>6 procedure in any event because the surgical</p> <p>7 site is always contaminated.</p> <p>8 Can you explain that to me?</p> <p>9 MR. SNELL: Form and foundation</p> <p>10 on your understanding of Ethicon.</p> <p>11 A. Well, I think that they mean</p> <p>12 grossly contaminated. If there is a gross</p> <p>13 infection or if there is some stool, you</p> <p>14 know, fistula, something where it's grossly</p> <p>15 contaminated, it would be contraindicated.</p> <p>16 But it's, you know, obviously you</p> <p>17 would have a hard time doing any kind of</p> <p>18 vaginal surgery if you couldn't do it -- if</p> <p>19 you're broadly defining contaminated as</p> <p>20 including clean-contaminated.</p> <p>21 BY MS. KIRKPATRICK:</p> <p>22 Q. So you will agree with me maybe</p> <p>23 that's not precisely worded --</p> <p>24 MR. SNELL: Form.</p>	<p style="text-align: right;">Page 154</p> <p>1 BY MS. KIRKPATRICK:</p> <p>2 Q. -- to reflect what you're</p> <p>3 describing, correct?</p> <p>4 MR. SNELL: Form.</p> <p>5 BY MS. KIRKPATRICK:</p> <p>6 Q. It doesn't say "grossly</p> <p>7 contaminated," does it?</p> <p>8 A. Right.</p> <p>9 Q. It doesn't say "fistula</p> <p>10 formation"?</p> <p>11 A. I mean, I think you have to take</p> <p>12 into account just surgical principles. I</p> <p>13 think that most surgeons would know what</p> <p>14 they're talking about.</p> <p>15 Q. You think that most surgeons</p> <p>16 would?</p> <p>17 A. Yeah.</p> <p>18 Q. Okay. Now, it says that</p> <p>19 postoperatively, the patient should be</p> <p>20 advised to refrain from heavy lifting and/or</p> <p>21 exercise -- examples, cycling and jogging --</p> <p>22 for at least three to four weeks after the</p> <p>23 surgery, and intercourse after one month.</p> <p>24 Patients can usually return to normal</p>
<p style="text-align: right;">Page 155</p> <p>1 activities after one to two weeks.</p> <p>2 What is heavy lifting?</p> <p>3 A. Well, I recommend to my patients</p> <p>4 conservatively more than 10 pounds lifting or</p> <p>5 any kind of straining that would put pressure</p> <p>6 on your pelvic floor that you can avoid.</p> <p>7 Q. And heavy lifting and exercise,</p> <p>8 now, you don't consider vacuuming either</p> <p>9 heavy lifting or exercise, do you?</p> <p>10 A. Well, it depends on the vacuum,</p> <p>11 yeah, it could be very heavy lifting.</p> <p>12 Q. Okay. Do you ask your patients</p> <p>13 or when you release them from TVT-O surgery,</p> <p>14 do you ask them what kind of vacuum they</p> <p>15 have?</p> <p>16 A. No, but I advise them to just</p> <p>17 avoid it altogether.</p> <p>18 Q. So this non -- minimally invasive</p> <p>19 surgery that allows women to return to normal</p> <p>20 activities quickly means that you they can't</p> <p>21 vacuum for a month?</p> <p>22 A. Yeah.</p> <p>23 Q. And you tell your patients that?</p> <p>24 A. Yeah. Avoid housework.</p>	<p style="text-align: right;">Page 156</p> <p>1 Q. What else do you tell -- avoid</p> <p>2 housework, okay. Can they do the dishes?</p> <p>3 A. Yeah. That's not straining their</p> <p>4 pelvis.</p> <p>5 Q. Can they make their bed?</p> <p>6 A. That depends. If they have a</p> <p>7 high bed, it's difficult to make, it may be</p> <p>8 too much strain.</p> <p>9 Q. And you tell them to restrain</p> <p>10 from that for a period of --</p> <p>11 A. I tell them six weeks.</p> <p>12 Q. Six weeks?</p> <p>13 A. Uh-huh, just to be super</p> <p>14 conservative.</p> <p>15 Q. Okay. What else do you tell them</p> <p>16 that they can't do?</p> <p>17 A. I tell them not to have</p> <p>18 intercourse for six weeks. I tell them to</p> <p>19 avoid any straining, cycling, that will put</p> <p>20 pressure on the pelvic area, squats.</p> <p>21 Q. Can they walk?</p> <p>22 A. They can walk, they can go</p> <p>23 upstairs slowly, if they, you know, just are</p> <p>24 cautious. They can ride in the car. I tell</p>

Christina Pramudji, M.D.

Page 157

1 them not to drive a car for the first three
2 days. They can ride in a car and they can go
3 back to work at three days if it's a desk job
4 or not too strenuous, if they feel up to it.
5 Q. Okay. So what about a physical
6 therapist? When would you advise a physical
7 therapist to go back to work?
8 A. Depends on what she's doing, but
9 I'd probably advise for her to -- you know,
10 if she's an aquatic physical therapist, to
11 wait about a week or two before she gets back
12 in the pool. It depends on what she's doing
13 with her patients, too. If she's actively
14 exercising, I would want her to avoid
15 anything strenuous with that.
16 Q. Okay.
17 A. But if she's just, you know, kind
18 of assisting them, watching them, that would
19 be fine.
20 Q. Okay. And you consider all of
21 those things to be either heavy lifting or
22 exercise or something that would place too
23 much strain on the pelvic floor and could
24 affect the sling itself?

Page 159

1 Dr. Pramudji, that this was information that
2 Ethicon deemed to be important to put in the
3 instructions for use, correct?
4 A. I would think so, yes.
5 Q. Okay. Do you see anywhere in
6 here that they warn -- well, let me ask you
7 this: What was the source of the 24- to
8 48-hour transitory leg pain?
9 A. I'm not exactly what source they
10 used for that but there's a few studies that
11 show that, you know, for the most part, it is
12 transitory leg pain.
13 Q. And you don't know what causes
14 it?
15 A. Oh, you mean what causes it.
16 Q. Oh, yes.
17 A. Oh, I'm sorry, I thought you
18 meant what they were citing.
19 Q. Oh, no, no, what causes it.
20 A. I apologize. Where the helical
21 trocar passes through the obturator foramen,
22 through those muscles that we talked about
23 earlier, they get irritated or maybe a nerve
24 root gets irritated, and we believe that's

Page 158

1 A. Yes.
2 Q. Okay. You also see here that
3 Ethicon talks about transient leg pain
4 lasting 24 to 48 hours may occur and can
5 usually be managed with mild analgesics. Do
6 you see that?
7 A. Yes.
8 Q. Now, does that basically mean you
9 should take some Motrin or some Advil if you
10 have some of this transitory pain?
11 A. That's typically what mild
12 analgesic would mean, Tylenol, ibuprofen.
13 Q. And it specifies 24 to 48 hours,
14 correct?
15 A. Yes.
16 Q. And you will agree with me that
17 Ethicon obviously believed this was important
18 information to put in the IFU to give to
19 physicians, and therefore --
20 (Knock on door, brief
21 interruption.)
22 (Discussion off the record.)
23 BY MS. KIRKPATRICK:
24 Q. So you'll agree with me,

Page 160

1 what causes the leg pain.
2 Q. What nerve -- can you tell me,
3 what muscles were those?
4 A. The -- just the obturator foramen
5 muscles, there's four or five.
6 Q. Okay. In what percentage of
7 cases do you see the transient leg pain
8 lasting for 24 to 48 hours? How many women
9 experience that as a complication of the
10 surgery?
11 A. In my practice, you mean, or --
12 Q. Well, why don't you give me your
13 practice and also tell me what your
14 understanding is from the medical literature.
15 A. I think the studies show, you
16 know, a range of values. It went up to --
17 like the Tang study, it was like a quarter of
18 patients and some of them are less, around 6
19 to 10%. I would say, you know, probably
20 somewhere in there would be a good number.
21 Q. Okay. So somewhere from 6% to
22 24% --
23 A. Uh-huh.
24 Q. -- I think is what we had.

40 (Pages 157 to 160)

Christina Pramudji, M.D.

Page 161

1 Now, do you see anywhere in this
2 IFU that Ethicon informs physicians that
3 patients can experience chronic pain after
4 insertion of the transobturator device?

5 MR. SNELL: Form.

6 Go ahead.

7 A. I don't think it's specifically
8 laid out, but they talk about the irritation
9 and inflammation and it's sort of a known
10 fact of surgical training that that can occur
11 after any surgery, to have chronic pain. So
12 it's kind of a commonsense knowledge of
13 surgeons.

14 BY MS. KIRKPATRICK:

15 Q. Does it say anywhere in this IFU
16 that one of the complications of this can be
17 dyspareunia?

18 A. I don't think it specifically
19 says that.

20 Q. Okay. Does it say anywhere in
21 here that there can be chronic pain in the
22 wall of the vagina for women who get this?

23 A. I don't believe it does.

24 Q. So the only pain that Ethicon

Page 162

1 identified is this transient leg pain, and
2 surgeons would know about that too, correct?

3 MR. SNELL: Form.

4 A. Well, I think because, as you
5 mentioned before, we don't typically go into
6 the obturator canal before this procedure
7 actually came out so that would be something
8 that they would want to highlight for
9 physicians so they didn't think, oh, did I do
10 something wrong.

11 No, it's just sort of the anatomy
12 there. It's a sensitive area and patients
13 will have leg pain, but it is typically
14 almost all the time transitory.

15 BY MS. KIRKPATRICK:

16 Q. Does it tell -- it tells
17 physicians in here how to manage this
18 transient leg pain, correct?

19 A. It does say to manage it with
20 mild analgesics.

21 Q. Does it tell physicians anywhere
22 in here how to manage chronic pain that may
23 result from the use of a TVT-O device?

24 A. No, it doesn't.

Page 163

1 Q. Does it tell physicians in any
2 way that women may be required to take
3 narcotics to manage pain following -- chronic
4 pain following a TVT-O implant?

5 A. No.

6 Q. Does it tell physicians that they
7 may have to be on prescription medication for
8 a significant period of time to control
9 chronic pain?

10 MR. SNELL: Form.

11 Go ahead.

12 A. No.

13 BY MS. KIRKPATRICK:

14 Q. Does it tell physicians anywhere
15 in here how to manage or treat women who have
16 dyspareunia as a result of the TVT-O implant?

17 A. No, because again, common sense
18 with pelvic floor surgeons, they're going to
19 know about all these things ahead of time.

20 Q. Okay. So you think that
21 everything is known about, except for this
22 transient leg pain, this is the only thing
23 that physicians need to be instructed about
24 concerning the TVT-O device?

Page 164

1 A. Well, what -- I think that that's
2 one thing that's unique to the procedure,
3 that surgeons may not have been able to
4 anticipate because they don't work in that
5 area commonly.

6 And so, like I said, the first
7 time it happens to you, you may think, oh, my
8 gosh, you know, what did I do. And then --
9 if they didn't tell you about this, but then
10 you realize, okay, that can occur, it's been
11 seen, it's not just me, and it can be managed
12 this way.

13 Q. Okay. How many women who have a
14 pubovaginal sling have you seen who have
15 chronic pain?

16 A. Well, I haven't seen that many
17 patients with pubovaginal slings. I have one
18 right now, actually, though, that has chronic
19 pain.

20 Q. What kind of pain does she have?

21 A. She has lower abdominal pain.

22 Q. And what's the source of her
23 pain?

24 A. She had an MRSA infection after

Christina Pramudji, M.D.

<p style="text-align: right;">Page 165</p> <p>1 the surgery.</p> <p>2 Q. Okay. So is it the MRSA the</p> <p>3 source of the infection or is it the</p> <p>4 pubovaginal sling itself?</p> <p>5 A. I don't know exactly. It could</p> <p>6 be the inflammatory response to the</p> <p>7 infection, it could be the surgery itself.</p> <p>8 It's hard to know.</p> <p>9 Q. Do you think that that will be</p> <p>10 chronic pain?</p> <p>11 A. I don't know yet. It's hard to</p> <p>12 say.</p> <p>13 Q. How long has she experienced it</p> <p>14 for?</p> <p>15 A. It's been about three or four</p> <p>16 months.</p> <p>17 Q. And you haven't been able to cure</p> <p>18 that?</p> <p>19 A. Huh-uh, not yet.</p> <p>20 Q. Have you sought out any advice</p> <p>21 from fellow physicians on how to deal with</p> <p>22 it?</p> <p>23 A. No.</p> <p>24 Q. Have you talked to anyone who</p>	<p style="text-align: right;">Page 166</p> <p>1 does a lot of pubovaginal slings and ask them</p> <p>2 if they have had this experience before?</p> <p>3 A. No.</p> <p>4 Q. You've been using a lot of</p> <p>5 anatomical terms, and I think you've been</p> <p>6 trying -- doing a very good job of trying to</p> <p>7 teach me anatomy, but I just want to make</p> <p>8 sure that we are all on the same page.</p> <p>9 So I'm going to mark this as</p> <p>10 Exhibit 10 and ask you to help me out here a</p> <p>11 little.</p> <p>12 (Whereupon, Exhibit Pramudji-10,</p> <p>13 Pelvic Illustration with Handwritten</p> <p>14 Labels, was marked for identification.)</p> <p>15 BY MS. KIRKPATRICK:</p> <p>16 Q. Okay. Can you, to orient us,</p> <p>17 this -- is this the view of a woman who</p> <p>18 you're looking up towards her pelvic area,</p> <p>19 correct?</p> <p>20 A. Uh-huh.</p> <p>21 Q. So this is the view that you</p> <p>22 would have during --</p> <p>23 A. This is looking down from above.</p> <p>24 It is looking into the pelvis from above.</p>
<p style="text-align: right;">Page 167</p> <p>1 Q. Into the -- okay. Can you</p> <p>2 explain that to me? Can you just label the</p> <p>3 urethra, the vagina and the rectum for me?</p> <p>4 MR. SNELL: No. She's not here</p> <p>5 to label things on documents. She's here</p> <p>6 to give testimony. She's not labeling</p> <p>7 this thing for you.</p> <p>8 MS. KIRKPATRICK: Well, yes, she</p> <p>9 is. This is a deposition.</p> <p>10 MR. SNELL: No, she's not.</p> <p>11 MS. KIRKPATRICK: Let's call the</p> <p>12 Court.</p> <p>13 MR. SNELL: Call the Court. This</p> <p>14 is not a labeling session. She's here to</p> <p>15 answer your questions.</p> <p>16 BY MS. KIRKPATRICK:</p> <p>17 Q. Well, I'll tell you what. Why</p> <p>18 don't you point it out to me and I'll label</p> <p>19 it and you tell me if I'm incorrect where</p> <p>20 I've labeled the information.</p> <p>21 MS. KIRKPATRICK: Can we do it</p> <p>22 that way?</p> <p>23 MR. SNELL: I have no problem</p> <p>24 with that. I have no problem with that,</p>	<p style="text-align: right;">Page 168</p> <p>1 but she's not here to write any labels.</p> <p>2 MR. WALLACE: Can you -- I'm</p> <p>3 sorry, I'll sit down.</p> <p>4 MR. SNELL: It's a deposition.</p> <p>5 It is a deposition. It is a</p> <p>6 question-and-answer session.</p> <p>7 MS. KIRKPATRICK: It's absurdity,</p> <p>8 but, you know, we can deal with people</p> <p>9 like that.</p> <p>10 A. So this is from the bottom. This</p> <p>11 is if you take out all the organs and look</p> <p>12 from above.</p> <p>13 BY MS. KIRKPATRICK:</p> <p>14 Q. Okay. So, hang on. Let me just</p> <p>15 make sure that you and I are oriented to the</p> <p>16 same place in the anatomy, and then I want to</p> <p>17 ask you about your report.</p> <p>18 A. Uh-huh.</p> <p>19 Q. So can you point out to me where</p> <p>20 the urethra is?</p> <p>21 A. Uh-huh.</p> <p>22 THE WITNESS: Can I see your pen</p> <p>23 for a second?</p> <p>24 BY MS. KIRKPATRICK:</p>

42 (Pages 165 to 168)

Christina Pramudji, M.D.

Page 169

1 Q. And by the way, you are able to
2 write, correct? And the only reason you're
3 not writing here is that Mr. Snell has told
4 you not to?
5 MR. SNELL: Yes.
6 BY MS. KIRKPATRICK:
7 Q. And I'm going to act as your
8 scribe for you today, so I hope my
9 handwriting is as good as yours.
10 A. It's this one right there.
11 Q. This line here, okay. So I have
12 labeled the urethra here where you told me to
13 label it, right?
14 A. Uh-huh.
15 Q. And then where is the vagina?
16 A. Right here.
17 Q. Have I correctly labeled the
18 vagina where you pointed it out to me?
19 A. Uh-huh.
20 Q. Okay. And then can you point at
21 the rectum for me?
22 A. Right here.
23 Why do you want to do this?
24 Q. Because I want to ask you about

Page 171

1 Q. Did I get that right?
2 A. Uh-huh.
3 Q. And did I label those two muscles
4 correctly?
5 A. Yes.
6 Q. Okay. And is this here -- this
7 almost looks like a triangle to me, is this a
8 separate muscle?
9 A. Yes.
10 Q. Okay. And what is this one?
11 A. That is going to be the -- I
12 believe that's the iliococcygeus.
13 Q. I-L-L?
14 A. I-L-I-O.
15 Q. Oh, I-L-I-O?
16 A. Uh-huh, C-O-C-C-Y-G-E-U-S.
17 Q. Okay. And what is this muscle
18 right at the bottom here?
19 A. That would be the -- I can't
20 remember at the moment.
21 Q. Okay. I'll just put a question
22 mark there. And then --
23 A. This would be the ischial spine.
24 Q. I-S-C-H-I --

Page 170

1 some of Ms. Huskey's anatomy so I just want
2 to make sure that we're all talking about the
3 same thing here.
4 A. Okay.
5 Q. Okay. So those are basically
6 stacked on top of each other. Is that right?
7 A. Uh-huh, correct.
8 Q. Okay. And what I'm pointing at
9 here, there's a number of muscles that are
10 identified here. Can you tell me what
11 muscles those are?
12 A. Sure. This is the puborectalis.
13 Q. This muscle down here, so if I
14 label this here -- can you spell that for me?
15 A. P-U-B-O-R-E-C-T-A-L-I-S.
16 Q. Okay. And then what is this
17 muscle? Is this a separate muscle?
18 A. Uh-huh.
19 Q. Okay. And what muscle is that?
20 A. That's going to be the
21 ischiococcygeus.
22 Q. Okay. You're going to have to
23 help me out there.
24 A. I-S-C-H-I-O-C-O-C-C-Y-G-E-U-S.

Page 172

1 A. A-L.
2 Q. -- A-L?
3 A. S-P-I-N-E.
4 This would be the ATPF.
5 Q. And can you tell me what that is?
6 A. Arcus, A-R-C-U-S, tendineus,
7 T-E-N-D-I-N-E-U-S -- E-U-S.
8 Q. Okay.
9 A. -- fascial pelvis.
10 Q. Okay. I will take credit for any
11 spelling errors on this.
12 A. This is the obturator fascia that
13 they're showing.
14 Q. Okay.
15 A. Obturator foramen.
16 Q. And that's where --
17 A. Where you want to avoid with the
18 helical trocar.
19 Q. You want to avoid the obturator
20 foramen?
21 A. Oh, yeah. That's where the main
22 branches of the -- that's where the nerves
23 are.
24 Q. Okay. And what is this up here?

43 (Pages 169 to 172)

1 A. The pubic symphysis.
2 Q. And that's a bone, correct?
3 A. It's a connective tissue.
4 Q. Okay. And then I don't know if
5 it's labeled here. What is this here?
6 A. That's the pelvic bone.
7 Q. The pelvic bone.
8 A. Uh-huh.
9 Q. Okay. And I think we labeled
10 this up here, but what is this structure down
11 here?
12 A. That's the perineal body.
13 Q. Now, these muscles that you've
14 identified for me, which of them are
15 considered part of the levator muscles?
16 A. All of them.
17 Q. Okay. So all of these muscles,
18 which would include the puborectalis, the
19 ischio- -- help me out here?
20 A. -- coccygeus.
21 Q. Okay. The ischial spine. Is
22 that right?
23 A. That's the point on the bone.
24 Q. Okay. The iliococcygeus and then

1 location that you have indicated that you
2 feel the -- I don't know exact -- I've got to
3 go back and take a look at it, but you felt
4 the band of --
5 A. Muscle spasm.
6 Q. Something.
7 A. Yes.
8 Q. Okay. So in that band that you
9 feel on the left vaginal wall you believe is
10 a muscle spasm?
11 A. Yeah, it's a muscle in spasm,
12 yes.
13 Q. Okay. It's a muscle in spasm.
14 A. Yes.
15 Q. Okay. And is this also the point
16 in the vaginal wall that you found
17 tenderness?
18 A. She was tender, yes, on that
19 spot.
20 Q. Is there anywhere else in the
21 vagina that she was tender?
22 A. She was a little tender right up
23 under here on the left side, and you can feel
24 a little scar tissue.

1 these muscles down here, this all forms the
2 levator muscles that support the pelvis,
3 correct?
4 A. Correct.
5 Q. Okay. So which of the muscles --
6 which of Mrs. Huskey's muscles on exam, I
7 think you indicated that she had levator
8 muscles that were spasming. Can you show me
9 which ones those are?
10 A. Right back here. Spasm right
11 there and it's kind of tilted I think because
12 of her SI joint problem, so you can see the
13 sling would have been like this, and this
14 muscle here is what's in spasm.
15 Q. Okay. So what you drew up here,
16 this top line here, this is the sling
17 placement?
18 A. Uh-huh. Yes.
19 Q. And this is the point of the
20 muscle spasm. Is that right?
21 A. Yeah, right here. It's a band.
22 You can feel it going across the left side of
23 her vagina. This is left and this is right.
24 Q. Okay. So this is also the

1 Q. Like here?
2 A. Uh-huh.
3 Q. Okay.
4 A. And then she was just mildly
5 tender just everywhere.
6 Q. She was mildly tender throughout?
7 A. Throughout her whole vagina, but
8 the main spot was here. That's what's really
9 bothering her.
10 Q. Okay. So we have an area of
11 tenderness in the vaginal wall here, and this
12 is a muscle spasm.
13 A. Uh-huh.
14 Q. Okay. Can you -- I just don't
15 want to misrepresent in any way what you've
16 testified about. Can you just double-check
17 that I have labeled all of that accurately?
18 A. Yes.
19 Q. Okay. I just want to make sure
20 we're all on the same page when we start
21 talking about lefts and rights and anteriores
22 and posteriors.
23 Okay. So looking at -- you
24 reviewed, I think we talked about, the

Christina Pramudji, M.D.

Page 177

1 depositions, you reviewed certain medical
 2 records and you also did an IME on
 3 Mrs. Huskey, correct?
 4 A. That's correct.
 5 Q. And you'll agree with me that
 6 prior to the implantation of her TVT-O, she
 7 was a very active woman, correct?
 8 A. Yes.
 9 Q. She exercised frequently?
 10 A. She -- I don't know how often she
 11 exercised, but she said she would do the
 12 elliptical for eight miles is what she told
 13 me.
 14 Q. Okay. And do you remember seeing
 15 in the medical records or the depositions
 16 that she would do that three to four times a
 17 week?
 18 A. Yeah, I think I do remember that,
 19 now that you mention it.
 20 Q. And she had also a fairly
 21 physically demanding job as a physical
 22 therapist, correct?
 23 A. Yes.
 24 Q. And she, prior to the surgery,

Page 179

1 that she had been dealing with.
 2 Q. Okay. And then, I'm sorry, I
 3 missed the last one that you had said.
 4 MR. SNELL: Pelvic pain, it says.
 5 MS. KIRKPATRICK: Pelvic pain,
 6 thank you.
 7 BY MS. KIRKPATRICK:
 8 Q. And she had reports of pelvic
 9 pain. Did you see any reports of chronic
 10 pelvic pain?
 11 A. I don't -- I can't remember. I
 12 don't believe so.
 13 Q. Okay. What type of pelvic pain
 14 was reported in Mrs. Huskey's medical records
 15 prior to the implantation of the TVT-O sling?
 16 A. It was left-sided pelvic pain and
 17 some rectal discomfort and dyspareunia. And
 18 she also told me at the IME that she had some
 19 deep central pain.
 20 Q. And you will agree that those
 21 were reported at an OR visit maybe three to
 22 four months prior to the implantation of her
 23 sling? Is that right?
 24 MR. SNELL: Form.

Page 178

1 was able to have intercourse with her
 2 husband?
 3 A. Yes.
 4 Q. Correct?
 5 And did you see in anything in
 6 her medical records prior to the implantation
 7 of the TVT-O device that Mrs. Huskey was in
 8 any way chronically physically limited in her
 9 ability to engage in daily activities?
 10 A. No, I don't believe I did. She
 11 had some chronic complaints, but I don't --
 12 there wasn't a limitation there.
 13 Q. Okay.
 14 A. She had chronic back pain, I
 15 believe she had some dyspareunia and some
 16 pelvic pain, especially on the left. But
 17 there wasn't a limitation.
 18 Q. So she had -- so let's go through
 19 the prior conditions that you've noted. You
 20 said she had chronic back pain, she had
 21 dyspareunia. Do you believe that that was --
 22 did you see reports of chronic dyspareunia?
 23 A. I can't remember how long that it
 24 went on ahead of time, but it was something

Page 180

1 A. An OR visit?
 2 BY MS. KIRKPATRICK:
 3 Q. Yes. I'm sorry, ER, yes.
 4 A. I believe so.
 5 Q. And Dr. Byrkit, her treating
 6 physician, actually saw her at that time,
 7 correct?
 8 A. I believe so, yes.
 9 Q. And those symptoms resolved
 10 themselves after that ER visit, didn't they?
 11 MR. SNELL: Form.
 12 A. I don't know if they did or not.
 13 BY MS. KIRKPATRICK:
 14 Q. Okay. And do you remember
 15 Dr. Byrkit determining that those were not
 16 GYN in origin?
 17 A. I think she thought that the left
 18 pelvic pain might have been related to the
 19 ovarian cyst at that time.
 20 Q. Okay. Do you remember that she
 21 ruled that out after the workup in the ER and
 22 dismissed -- or discharged Mrs. Huskey and
 23 made a notation that there was no GYN origin
 24 to that particular visit, correct?

45 (Pages 177 to 180)

<p style="text-align: right;">Page 181</p> <p>1 A. Correct.</p> <p>2 Q. And that was an acute incident,</p> <p>3 correct?</p> <p>4 A. I believe so, yeah. But I think</p> <p>5 she had been having some complaints prior to</p> <p>6 that when she had sought care, I can't</p> <p>7 remember, it was a while back when she was</p> <p>8 concerned about her hormonal status and being</p> <p>9 evaluated for some pelvic pain and</p> <p>10 dyspareunia a couple of years before that.</p> <p>11 Q. And you think that there was a</p> <p>12 connection between that office visit and her</p> <p>13 ER visit a few months before she had the</p> <p>14 TVT-O?</p> <p>15 A. There could have been.</p> <p>16 Q. Could have been, or was?</p> <p>17 A. Pelvic pain is very -- as we</p> <p>18 talked about before, it's so complicated with</p> <p>19 the overlap of the organs in that area, I</p> <p>20 think they chalked it up, the ER visit, to</p> <p>21 diverticulosis at that time.</p> <p>22 Q. Do you have any reason to</p> <p>23 disagree with that diagnosis?</p> <p>24 A. No. The only thing that -- well,</p>	<p style="text-align: right;">Page 182</p> <p>1 I guess I do, because when I examined her and</p> <p>2 talked to her, she has, as I mentioned in my</p> <p>3 report, she does have bladder pain and pain</p> <p>4 with filling, which indicates a possible</p> <p>5 chronic bladder disorder and chronic</p> <p>6 upregulation of the pelvic pain receptors.</p> <p>7 So there could be some</p> <p>8 relationship there with how the nerves are</p> <p>9 cross-reacting and it could be something</p> <p>10 that's kind of been developing over time.</p> <p>11 Q. And you agree with me that the</p> <p>12 nerves in the pelvis do cross-react, correct?</p> <p>13 A. Yes.</p> <p>14 Q. What is your definition of</p> <p>15 chronic pelvic pain?</p> <p>16 A. Chronic pelvic pain would last --</p> <p>17 typically we consider it, in general in</p> <p>18 medicine, more than six months, is considered</p> <p>19 chronic, and it could be any pain in the</p> <p>20 pelvic area. It may not be continuous, it</p> <p>21 could be intermittent, but it's anywhere in</p> <p>22 the pelvis that could be coming and going for</p> <p>23 at least six months.</p> <p>24 Q. Okay. And in your practice as a</p>
<p style="text-align: right;">Page 183</p> <p>1 urologist, what do you treat that can be the</p> <p>2 causes of chronic pelvic pain?</p> <p>3 A. I treat interstitial cystitis,</p> <p>4 pelvic floor muscle dysfunction or levator</p> <p>5 spasm, postsurgical pain from various</p> <p>6 sources. I have a few patients with</p> <p>7 dyspareunia, urogenital atrophy, urethritis,</p> <p>8 kidney stones or ureteral stones, to be</p> <p>9 precise.</p> <p>10 Q. Anything else?</p> <p>11 A. Those would be the main</p> <p>12 categories of patients that I can think of.</p> <p>13 Q. Okay. So I want to go back for a</p> <p>14 second to dyspareunia. Dyspareunia is</p> <p>15 generally a symptom of some type of pelvic</p> <p>16 pain, correct?</p> <p>17 A. Correct.</p> <p>18 Q. And what are the causes of</p> <p>19 dyspareunia that you treat in your practice?</p> <p>20 A. Uh-huh. Urogenital atrophy,</p> <p>21 interstitial cystitis, urethritis, pelvic</p> <p>22 floor muscle spasm.</p> <p>23 Q. Anything else?</p> <p>24 A. Postsurgical scarring. That's</p>	<p style="text-align: right;">Page 184</p> <p>1 all I can think of at the moment.</p> <p>2 Q. Okay. Did Mrs. Huskey have</p> <p>3 urogenital atrophy?</p> <p>4 A. Yes.</p> <p>5 Q. Do you think that's the cause of</p> <p>6 her dyspareunia?</p> <p>7 A. I don't think it's the main</p> <p>8 cause, but I think it's probably</p> <p>9 contributing.</p> <p>10 Q. How do you treat dyspareunia</p> <p>11 caused by urogenital atrophy?</p> <p>12 A. Typically use either vaginal</p> <p>13 estrogen cream or tablets, or there's a new</p> <p>14 medication called Osphena that I've used,</p> <p>15 O-S-P-H-E-N-A, that I've used a couple of</p> <p>16 times. It's new.</p> <p>17 Q. Do you believe that Mrs. Huskey's</p> <p>18 dyspareunia is caused by postsurgical</p> <p>19 scarring?</p> <p>20 A. I think some of it is, but no.</p> <p>21 Most of it's the levator spasm that she has.</p> <p>22 Q. Okay. So when you say some of</p> <p>23 it, is the postsurgical scarring would be</p> <p>24 secondary to either the TVT-O implant,</p>

<p style="text-align: right;">Page 185</p> <p>1 explant or both, correct?</p> <p>2 A. Correct.</p> <p>3 Q. And you'll agree with me that</p> <p>4 that surgery has caused some scarring in her</p> <p>5 pelvis?</p> <p>6 A. It has minimal scarring right</p> <p>7 under the urethra.</p> <p>8 Q. And that that postsurgical</p> <p>9 scarring can be a cause of her dyspareunia,</p> <p>10 even if it's not the main cause, correct?</p> <p>11 MR. SNELL: Form.</p> <p>12 A. It's such minimal scarring, it's</p> <p>13 possible, but it's very unlikely. I think if</p> <p>14 someone didn't know she had surgery and</p> <p>15 examined her, they wouldn't be able to really</p> <p>16 tell any difference.</p> <p>17 BY MS. KIRKPATRICK:</p> <p>18 Q. Okay. Do you -- so let's talk</p> <p>19 about the pelvic floor muscle spasm. That is</p> <p>20 the levator muscles, correct, throughout the</p> <p>21 entire pelvic region. And you've identified</p> <p>22 Mrs. Huskey's muscle spasm as occurring on</p> <p>23 the left -- basically the left wall of the</p> <p>24 vagina, correct?</p>	<p style="text-align: right;">Page 186</p> <p>1 A. Yes. Left posterior wall. And</p> <p>2 it's abnormally angled.</p> <p>3 Q. The muscle is abnormally angled?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And this muscle spasm that</p> <p>6 you say you believe that that is a cause of</p> <p>7 her dyspareunia, correct?</p> <p>8 A. That's where her pain is coming</p> <p>9 from.</p> <p>10 Q. Okay. What's the cause of that</p> <p>11 muscle spasm?</p> <p>12 A. That muscle spasm, I suspect it's</p> <p>13 related to the SI joint issue that she has</p> <p>14 causing pelvic tilt. She wears a belt all</p> <p>15 the time. She has a slightly abnormal gait.</p> <p>16 I don't know if that goes back to the motor</p> <p>17 vehicle accident she was in. And I think</p> <p>18 just the overall upregulation in her pelvic</p> <p>19 area, I think the stress, that's where she's</p> <p>20 carrying her stress that she's under. You</p> <p>21 know, it's like some people carry it in their</p> <p>22 neck muscles where they'll get a tight neck</p> <p>23 or a headache, some people carry it in their</p> <p>24 pelvic floor muscles, that's where their</p>
<p style="text-align: right;">Page 187</p> <p>1 stress will manifest, and she's a very</p> <p>2 stressed person. Seemed somewhat depressed,</p> <p>3 in my opinion. And so I think that's</p> <p>4 exacerbating it, not causing it but</p> <p>5 exacerbating it.</p> <p>6 I do not think it's from the</p> <p>7 sling, because it's just not anywhere near</p> <p>8 where the sling traverses and, really, that</p> <p>9 was not really described in her medical</p> <p>10 records or by her until after the sling was</p> <p>11 actually explanted.</p> <p>12 Q. Okay. So let's talk about this</p> <p>13 in a little more detail. Now, these muscles</p> <p>14 that we've identified here, where do they</p> <p>15 insert?</p> <p>16 MR. SNELL: Form.</p> <p>17 A. What do you mean?</p> <p>18 BY MS. KIRKPATRICK:</p> <p>19 Q. Do they insert into the bones, do</p> <p>20 they insert -- where do they go?</p> <p>21 A. Well, you can see on the picture</p> <p>22 right there where they go.</p> <p>23 Q. Is this the end of the muscle?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 188</p> <p>1 Q. Okay. So the muscle ends here</p> <p>2 and it's connected to what?</p> <p>3 A. The bones and the ligaments right</p> <p>4 there.</p> <p>5 Q. These bones and ligaments, the</p> <p>6 pubic bone here, and which ligaments are</p> <p>7 these?</p> <p>8 A. That's the ATFP and the obturator</p> <p>9 fascia.</p> <p>10 Q. And the sling itself goes through</p> <p>11 the obturator fascia, right?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. And that's actually how</p> <p>14 it's implanted, correct?</p> <p>15 A. That's how it's -- what do you</p> <p>16 mean, that's how it's implanted?</p> <p>17 Q. Through the fascia?</p> <p>18 A. That's the design of it, to go</p> <p>19 through that --</p> <p>20 Q. Yes, thank you.</p> <p>21 A. -- fascia and through those</p> <p>22 muscles.</p> <p>23 Q. Okay. And what we know from</p> <p>24 Dr. Siddique's report is when he went in to</p>

1 remove her sling, he pulled down on it, as
 2 you said, right, and then when he let go, he
 3 described it as retracting behind the pubic
 4 bone, correct?
 5 A. Yes.
 6 Q. So we know that there's some
 7 portion of the mesh that still exists in this
 8 location through the obturator foramen and
 9 back behind this pubic bone, correct?
 10 A. Correct.
 11 Q. And that's the same obturator
 12 foramen that the muscles, the levator
 13 muscles, insert through, correct? Or attach
 14 to?
 15 A. Not really. I mean, you can see
 16 where they sort of --
 17 Q. Show me where that is.
 18 A. They sort of come over here to
 19 this point, but then they end and they're not
 20 really near this fascia here, these muscles.
 21 Q. How much distance is there
 22 between that -- this muscle here and that
 23 fascia there? How many centimeters is that?
 24 A. Well, the fascia goes right up to

1 Q. Okay. So this is the fascia --
 2 A. But that line is like a wall
 3 that -- kind of a partition between the two
 4 compartments. These are considered different
 5 compartments.
 6 Q. But they're attached, correct?
 7 A. They're attached.
 8 Q. So this muscle attaches to this
 9 fascia here, and the sling, when it's
 10 implanted, goes in through the levator muscle
 11 here and it goes into the fascia as well,
 12 correct?
 13 MR. SNELL: Form.
 14 Go ahead.
 15 A. Yes.
 16 BY MS. KIRKPATRICK:
 17 Q. Now, putting aside this muscle
 18 spasm here, you said there's a point of
 19 tenderness that we've identified on this
 20 right here. What do you think is causing
 21 that tenderness?
 22 A. She's got some scar tissue right
 23 under there.
 24 Q. And is that scar tissue from the

1 that point and then the muscles start.
 2 Q. And they're all connected,
 3 correct?
 4 A. Yeah. They're opposing to each
 5 other, they're not necessarily connected but
 6 they're in the vicinity of each other.
 7 Q. Okay. And they work in
 8 conjunction with each other, don't they, to
 9 perform --
 10 A. This is kind of a separate
 11 compartment but this works as a floor. This
 12 all works together. But the obturator is a
 13 separate --
 14 Q. Okay. And I'm sorry that you're
 15 giving me an anatomy lesson.
 16 A. That's okay.
 17 Q. But I'm trying to understand
 18 here. Does this muscle connect to this
 19 fascia or not?
 20 A. The fascia --
 21 MR. SNELL: Form.
 22 A. -- condenses right there and
 23 makes a line and it attaches to that line.
 24 BY MS. KIRKPATRICK:

1 implant or explant surgery?
 2 MR. SNELL: Form.
 3 A. Yes.
 4 BY MS. KIRKPATRICK:
 5 Q. Okay. And you believe that that
 6 is the cause of the tenderness that she's
 7 feeling in this --
 8 A. That one spot.
 9 Q. -- one spot?
 10 A. Yes.
 11 Q. And it's the spot that sits
 12 between the urethra and the vagina, correct?
 13 A. Correct.
 14 Q. Okay.
 15 A. It's kind of right on the vaginal
 16 wall. There's a little bump, and that's
 17 where she's tender.
 18 Q. Okay. She's tender on that. And
 19 that is also contributing to the dyspareunia
 20 that she experiences, correct?
 21 A. It's hard to say. It could be.
 22 Q. Okay. At least --
 23 A. I mean, if that's all she had --
 24 Q. I'm not asking you if it's the

Page 193

1 cause, the only cause, the only thing that's
2 giving her discomfort, but that's something
3 that's contributing to the dyspareunia and
4 the discomfort that she's having vaginally,
5 correct?

6 MR. SNELL: Form.

7 A. It could be, yes.

8 BY MS. KIRKPATRICK:

9 Q. Okay. So let me go through with
10 you, then, this area of muscle spasm. I want
11 to just do a timeline so I can understand, in
12 my mind, how this would work.

13 Now, you'll agree with me that
14 she didn't have any reports of any muscle --
15 do you need to take that?

16 A. Yes. It's one of my partners.

17 MS. KIRKPATRICK: Sure. No

18 problem. We'll take a five-minute break.

19 (Recess, 2:31 p.m. to 2:50 p.m.)

20 BY MS. KIRKPATRICK:

21 Q. So I want to go through some of
22 the other -- the history and get a timeline
23 from you of when Ms. Huskey had certain
24 issues.

Page 194

1 A. Okay.

2 Q. So I think some of the issues
3 that you had talked about that you thought
4 were important or relevant to the diagnosis
5 of pelvic pain here were the back surgery
6 that she had?

7 A. Uh-huh.

8 Q. When did she have that back
9 surgery, do you remember?

10 A. She had two. She had one I
11 believe in '97 and one in 2000.

12 Q. '97 and 2000.

13 A. Uh-huh.

14 Q. And was that her upper, her
15 middle or her lower back?

16 A. Lower back.

17 Q. Okay. Do you believe that the
18 back surgery that she had in 1997 and 2000
19 has any correlation or any connection to the
20 pelvic pain that she's currently
21 experiencing?

22 A. I'm not -- I'm not sure about
23 that. It's a possible etiology. I think her
24 pain is multifactorial. It's hard to really

Page 195

1 dissect it out completely.

2 Q. Okay, so hard to dissect out.

3 But would you agree with me that
4 you can't say to a reasonable degree of
5 medical certainty that the back surgery in
6 1997 is causally related to her current
7 pelvic pain issues?

8 MR. SNELL: Form.

9 A. I can't say that it's not either.

10 BY MS. KIRKPATRICK:

11 Q. Okay. But I'm asking if you can
12 say that it is.

13 A. I can't say one way or another.

14 Q. Can't say one way or the other,
15 okay.

16 A. No.

17 Q. You also had referenced a
18 shoulder injury. Is that right?

19 (Brief interruption.)

20 MS. KIRKPATRICK: I'm sorry,
21 that's me. I'm sorry.

22 BY MS. KIRKPATRICK:

23 Q. I thought you had referenced
24 another surgery that she had. Am I incorrect

Page 196

1 in that?

2 A. No, I didn't.

3 Q. Okay, no other surgery.

4 And when you say that her pelvic
5 pain is multifactorial, I just want to make
6 sure that I have a complete, full listing of
7 each of the things that you believe are
8 contributing to her current pelvic pain.

9 A. The diverticulosis -- well,
10 number one at the top would be the levator
11 spasm.

12 Q. And you believe that the cause of
13 the levator spasm was the S1 joint issue?

14 A. I think that might be
15 contributing, because, like I said, it's
16 abnormally angled. I think she might have
17 some pelvic tilt issues.

18 Q. Okay. Anything else -- let's
19 take the levator spasm first. Anything else
20 that you believe can be causing the levator
21 spasm?

22 A. Well, like I said before, it can
23 be exacerbated by stress, can cause a muscle
24 spasm. The pain, you know, just the chronic

Page 197

1 pain, the pelvic surgery can -- any pelvic
2 surgery can contribute but the pelvic surgery
3 she had could contribute.

4 Q. Okay. Anything else? We've got
5 the pelvic surgery, that's the TVT-O surgery.
6 We have the potential S1 joint issue.

7 A. Uh-huh.

8 Q. Okay. We have that it may be
9 then exacerbated by stress but not caused by
10 stress. Is that right?

11 A. We don't really know for sure how
12 it all interplays, nobody has been able to
13 quite figure that out. I mean, I've seen
14 patients before that it just occurred at the
15 time of stress, there was no inciting factor.
16 They just had a lot of stress and then they
17 developed this pelvic floor spasm.

18 Q. Okay. Anything else that you
19 think is a cause of the levator muscle spasms
20 that she is experiencing?

21 A. I know she's had also some
22 problems with rectal pain with the
23 diverticulosis and there might be some
24 interplay there as well. But it's one of

Page 199

1 is the back surgery from '97 to 2000. Is
2 that right?

3 A. Uh-huh.

4 Q. Is there anything else -- okay.
5 So that's the levator spasm.

6 A. Uh-huh.

7 Q. Then separate and apart from
8 that, you talked about the diverticulosis,
9 right?

10 A. Uh-huh.

11 Q. And that was the diagnosis that
12 she had when coming from the emergency or
13 from her emergency room visit, I believe it
14 was the December time frame?

15 A. 2010, yes.

16 Q. December 2010, okay. And you
17 will agree with me that at that time, her
18 treating gynecologist ruled out a GYN origin
19 to that particular lower quadrant pain?

20 A. I'd have to look at the records
21 again. I can't remember exactly what her
22 conclusion was about that, but I do recall
23 that the overall thought was that it was the
24 diverticulosis because it was more on the

Page 198

1 those areas where usually you can't figure
2 out exactly what causes it.

3 Q. So am I correct in saying that
4 your opinion is that there's not a single
5 cause to the muscle spasm that she was
6 experiencing, but there are multiple causes
7 that working in connection with each other
8 are causing this muscle spasm that she's
9 having? Is that right?

10 A. Correct, uh-huh.

11 Q. And then that muscle spasm that
12 she's having is the source of most of her
13 both dyspareunia and chronic pelvic pain that
14 she's currently having?

15 A. Correct.

16 Q. Okay. And you gave me then a
17 list of the issues or a list of the
18 conditions that you believe were all working
19 in conjunction with each other to cause this
20 levator muscle spasm?

21 A. Correct.

22 Q. Is that right?

23 A. Yes.

24 Q. Okay. So what's not on that list

Page 200

1 left.

2 Q. Okay. And you also recall that
3 there were reports in her medical records
4 after that, that she controls the
5 diverticulosis by a diet and she's also, I
6 believe, on MiraLAX. Is that correct?

7 A. Yes.

8 Q. Okay. And is there any report
9 after December of 2010 that leads you to
10 believe that the diverticulosis is not being
11 controlled by the measures that she's
12 currently taking?

13 A. There was -- there was a time
14 when she was concerned about the
15 diverticulosis flaring up.

16 Q. Okay. And when was that?

17 A. I don't remember, 2012 or '13. I
18 can't recall. She was going to see her GI
19 doctor.

20 Q. And will you agree with me that
21 when you have diverticulosis, it is, as you
22 termed it, you generally have a flare-up? Is
23 that right?

24 A. Typically.

<p style="text-align: right;">Page 201</p> <p>1 Q. And then it's typically</p> <p>2 controlled by your diet, by exercise, and by</p> <p>3 medication after that. Is that right?</p> <p>4 A. Well, yeah. Keeping the bowel</p> <p>5 movements moving. She has chronic</p> <p>6 constipation, so, you know, it's hard to know</p> <p>7 how often it's contributing to her pain and</p> <p>8 discomfort because she doesn't keep it</p> <p>9 managed very well at all times. She doesn't</p> <p>10 have bowel movements regularly every day.</p> <p>11 Q. Okay. And that's even more</p> <p>12 difficult for her now since she's not</p> <p>13 exercising like she used to, because that</p> <p>14 helps keep your bowel movements regular,</p> <p>15 correct?</p> <p>16 MR. SNELL: Form.</p> <p>17 A. It does in most people.</p> <p>18 BY MS. KIRKPATRICK:</p> <p>19 Q. And actually, she has reported</p> <p>20 that that was helpful to her at a particular</p> <p>21 period in time in keeping her bowel habits</p> <p>22 regular, do you remember?</p> <p>23 A. I don't recall reading that.</p> <p>24 Q. You don't recall reading that?</p>	<p style="text-align: right;">Page 202</p> <p>1 A. No.</p> <p>2 Q. Did you ask her anything about it</p> <p>3 at your --</p> <p>4 A. No, we didn't talk about that.</p> <p>5 Q. But based on your review -- I</p> <p>6 should say this: At the examination, you</p> <p>7 didn't think that the diverticulosis or the</p> <p>8 chronic constipation were important enough to</p> <p>9 address with Mrs. Huskey at the IME, correct?</p> <p>10 A. We did address it. We didn't go</p> <p>11 into detail with it.</p> <p>12 Q. Okay. You didn't think it was</p> <p>13 important enough to go into detail with her</p> <p>14 about it at that time, did you?</p> <p>15 A. Yes. And she didn't mention</p> <p>16 anything more about it either.</p> <p>17 Q. And there were other issues that</p> <p>18 you considered to be more significant to the</p> <p>19 diagnosis of the pelvic pain than those</p> <p>20 particular issues, right?</p> <p>21 A. Correct, uh-huh.</p> <p>22 Q. So we talked about the levator</p> <p>23 spasms. Let me ask you this: This S1 joint</p> <p>24 issue, because I think I've asked you -- let</p>
<p style="text-align: right;">Page 203</p> <p>1 me get back to this.</p> <p>2 When did Mrs. Huskey first treat</p> <p>3 for S1 joint issues?</p> <p>4 A. I'd have to refresh my memory by</p> <p>5 looking at the medical records. I don't</p> <p>6 recall.</p> <p>7 Q. Do you remember generally that it</p> <p>8 was significantly before she had the TVT-O</p> <p>9 sling implanted?</p> <p>10 A. I don't. I really don't recall.</p> <p>11 I'd have to look.</p> <p>12 Q. And do you recall that she had</p> <p>13 been treated for several years on and off for</p> <p>14 that condition?</p> <p>15 A. That's my impression, yes.</p> <p>16 Q. Okay. And the SI issues that she</p> <p>17 had been treating for had never, during the</p> <p>18 entire period of time that she was treating</p> <p>19 for them, caused a levator muscle spasm,</p> <p>20 correct?</p> <p>21 MR. SNELL: Object to form.</p> <p>22 A. I don't -- I don't know.</p> <p>23 BY MS. KIRKPATRICK:</p> <p>24 Q. Okay. You didn't see anything in</p>	<p style="text-align: right;">Page 204</p> <p>1 her medical record that indicated the type of</p> <p>2 muscle spasm that we're seeing today and the</p> <p>3 tenderness in the vagina, she had ever</p> <p>4 experienced anything like that before,</p> <p>5 correct?</p> <p>6 A. There was nothing like that</p> <p>7 documented until after the explant.</p> <p>8 Q. Okay. So if it is the SI joint</p> <p>9 issue, she treated for many years with that</p> <p>10 without having this type of issue, and it</p> <p>11 didn't come to pass until I think it was</p> <p>12 about six weeks after she had the explant</p> <p>13 surgery? Is that right?</p> <p>14 A. Correct.</p> <p>15 Q. Okay.</p> <p>16 A. But oftentimes joint issues like</p> <p>17 that are progressive and things can shift. I</p> <p>18 don't -- like I said, I don't know if that's</p> <p>19 the exact cause, but that could be</p> <p>20 contributing.</p> <p>21 Q. Okay.</p> <p>22 A. It certainly -- as I said, that</p> <p>23 muscle is abnormally angled, it is not in the</p> <p>24 normal position that I've seen in other</p>

Christina Pramudji, M.D.

<p style="text-align: right;">Page 205</p> <p>1 patients, and that would make the most sense,</p> <p>2 that things are -- her pelvis is tilted.</p> <p>3 Q. How many women in the general</p> <p>4 population have a tilted pelvis?</p> <p>5 A. I don't know.</p> <p>6 Q. Is it a fairly common condition?</p> <p>7 A. No.</p> <p>8 Q. It's not?</p> <p>9 A. No.</p> <p>10 Q. Okay. Apart from -- I want to</p> <p>11 get back to this multifactorial pelvic pain.</p> <p>12 We dealt with the pelvic pain caused by the</p> <p>13 levator spasm and I think that was, again,</p> <p>14 multifactorial. There's several conditions</p> <p>15 that were kind of coming together that caused</p> <p>16 that spasm, correct?</p> <p>17 A. (Witness nods head.)</p> <p>18 Q. And then she's also having pain</p> <p>19 because of the diverticulosis, we talked</p> <p>20 about that. And then we also had previously</p> <p>21 talked about this point tenderness between</p> <p>22 the urethra and the vagina.</p> <p>23 Apart from those three issues, is</p> <p>24 there anything else, in your mind, that is</p>	<p style="text-align: right;">Page 206</p> <p>1 the cause of any of the pelvic pain that</p> <p>2 she's experiencing?</p> <p>3 A. The urogenital atrophy.</p> <p>4 Q. And what kind of pelvic pain do</p> <p>5 you think the urogenital atrophy is causing?</p> <p>6 A. I think it's causing just general</p> <p>7 tenderness in the area, from the tissues</p> <p>8 being a little thinned out.</p> <p>9 Q. Okay. Anything else?</p> <p>10 A. I don't think she's ever had a</p> <p>11 laparoscope to rule out endometriosis.</p> <p>12 That's on the differential. It doesn't sound</p> <p>13 like endometriosis but it's something that</p> <p>14 would be on a long differential diagnosis</p> <p>15 list.</p> <p>16 Q. Okay. So let's talk a little bit</p> <p>17 about endometriosis. Can you tell me what</p> <p>18 that is? You're better qualified than I am.</p> <p>19 A. Yes. It's abnormal endometrial</p> <p>20 tissue in the pelvic cavity.</p> <p>21 Q. Okay. And endometrial tissue is</p> <p>22 basically the uterine lining, correct?</p> <p>23 A. Correct.</p> <p>24 Q. And it's when the uterine lining</p>
<p style="text-align: right;">Page 207</p> <p>1 is not contained to the uterus itself but</p> <p>2 also grows outside in tissues in the pelvis.</p> <p>3 A. Yes.</p> <p>4 Q. What is the treatment for</p> <p>5 endometriosis?</p> <p>6 A. Well, either ablation of the</p> <p>7 lesions in the pelvis laparoscopically by</p> <p>8 burning them, cauterizing them, or hormonal</p> <p>9 therapy.</p> <p>10 Q. Okay. And isn't one way that you</p> <p>11 deal with endometriosis is through a</p> <p>12 hysterectomy?</p> <p>13 A. Sometimes that can be done.</p> <p>14 Q. Okay. And at the time that you</p> <p>15 have a hysterectomy performed, a physician</p> <p>16 would be able to see if the endometrial</p> <p>17 lining was growing outside of the uterus,</p> <p>18 correct?</p> <p>19 A. Depends on how the hysterectomy</p> <p>20 is performed. If it's a vaginal</p> <p>21 hysterectomy, they probably wouldn't be able</p> <p>22 to see anything.</p> <p>23 Q. Okay. But you'll agree with me</p> <p>24 that the removal of the uterus or the</p>	<p style="text-align: right;">Page 208</p> <p>1 hysterectomy is one way of dealing with</p> <p>2 problems related to endometriosis, correct?</p> <p>3 A. It is, but patients can still</p> <p>4 have endometrial tissue outside that was not</p> <p>5 recognized and can still be problematic.</p> <p>6 Q. That's basically hypothetical.</p> <p>7 You haven't seen any evidence in</p> <p>8 Mrs. Huskey's medical records at all that she</p> <p>9 had any problems with endometriosis, correct?</p> <p>10 MR. SNELL: Form.</p> <p>11 A. I don't -- I can't recall if that</p> <p>12 was addressed by one of her gynecologists</p> <p>13 right off the top of my head. I just kind of</p> <p>14 have that in the back of my mind on the</p> <p>15 differential diagnosis.</p> <p>16 BY MS. KIRKPATRICK:</p> <p>17 Q. Okay. And you know that she's</p> <p>18 had a hysterectomy?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. And you didn't note</p> <p>21 anything in the medical records, the</p> <p>22 hysterectomy or at the time of the</p> <p>23 hysterectomy that there was any concern with</p> <p>24 endometriosis?</p>

52 (Pages 205 to 208)

<p style="text-align: right;">Page 209</p> <p>1 A. Correct.</p> <p>2 Q. And that wasn't the reason for</p> <p>3 the hysterectomy?</p> <p>4 A. Right.</p> <p>5 Q. Okay. So you can't point me to</p> <p>6 anything in her medical records that would</p> <p>7 support the hypothesis that she has -- she</p> <p>8 may have endometriosis, correct?</p> <p>9 MR. SNELL: Form.</p> <p>10 A. Only the pelvic pain would be the</p> <p>11 only thing that would be a possible symptom</p> <p>12 of it.</p> <p>13 BY MS. KIRKPATRICK:</p> <p>14 Q. Okay. You will also agree with</p> <p>15 me that at the time Mrs. Huskey had her</p> <p>16 hysterectomy, she had -- it was observed that</p> <p>17 she had normal ovaries at that time, correct?</p> <p>18 A. I'd have to refresh my memory on</p> <p>19 that.</p> <p>20 Q. Okay. And generally, you would</p> <p>21 also agree with me that if you can visualize</p> <p>22 the ovaries at the time of a hysterectomy and</p> <p>23 that's reflected in her medical records, it's</p> <p>24 a good indication that you can visualize the</p>	<p style="text-align: right;">Page 210</p> <p>1 pelvic cavity and see whether there's any</p> <p>2 problem with endometrial tissue, correct?</p> <p>3 MR. SNELL: Form.</p> <p>4 A. Sure.</p> <p>5 BY MS. KIRKPATRICK:</p> <p>6 Q. Okay. And are you aware of any</p> <p>7 reports in the medical literature or any</p> <p>8 reports elsewhere of endometriosis developing</p> <p>9 for the first time after a hysterectomy was</p> <p>10 performed?</p> <p>11 A. No, I'm not aware of that.</p> <p>12 Q. Okay. So anything else that you</p> <p>13 believe is contributing or causing pelvic</p> <p>14 pain for Mrs. Huskey?</p> <p>15 A. No.</p> <p>16 Q. Okay. Now, I think you testified</p> <p>17 that -- and it's actually in your IME as</p> <p>18 well -- that Mrs. Huskey had some relief of</p> <p>19 the pain following the -- immediately</p> <p>20 following the removal of the sling, correct?</p> <p>21 A. Correct.</p> <p>22 Q. And that was for a period of</p> <p>23 about six weeks after the surgery?</p> <p>24 A. Correct.</p>
<p style="text-align: right;">Page 211</p> <p>1 Q. And it was when she went back to</p> <p>2 have a pelvic exam done when the speculum was</p> <p>3 put into her vagina, it caused -- or I</p> <p>4 shouldn't say -- it triggered pain in the</p> <p>5 vagina. Is that right?</p> <p>6 A. Leading up to the surgery that</p> <p>7 Dr. Siddique did, she had kind of deep</p> <p>8 central pain and pain around the area of mesh</p> <p>9 exposure, where it was rubbing, causing an</p> <p>10 irritation there. That's what she described.</p> <p>11 That's what was kind of described in the</p> <p>12 medical records and with the IME.</p> <p>13 The pain after it was removed,</p> <p>14 upon the speculum examination, was a</p> <p>15 different pain. It was a vaginal pain, a</p> <p>16 spasm pain, and that's what she's dealing</p> <p>17 with now and that's what we're observing on</p> <p>18 examination. So it changed. It was a</p> <p>19 different -- a different kind of pain, a</p> <p>20 different area of pain. You.</p> <p>21 Know, with Dr. Byrkit's records,</p> <p>22 you know, the pain was with intercourse,</p> <p>23 there wasn't this complaint of this chronic</p> <p>24 pain other than some -- you know, sometimes</p>	<p style="text-align: right;">Page 212</p> <p>1 that deep central pain.</p> <p>2 The other thing that I just</p> <p>3 thought about was on that list of the</p> <p>4 possible sources of pelvic pain, did you</p> <p>5 write down again the interstitial cystitis?</p> <p>6 Q. No, I didn't.</p> <p>7 A. The possibility that we talked</p> <p>8 about earlier?</p> <p>9 Q. Okay. Great, I want to talk</p> <p>10 about that too, thank you.</p> <p>11 A. Because when I did the</p> <p>12 urodynamics, she had pain with bladder</p> <p>13 filling, when her bladder got full, and</p> <p>14 there's not too many things that cause that.</p> <p>15 But interstitial cystitis is the main thing</p> <p>16 that causes that.</p> <p>17 Q. Okay.</p> <p>18 A. And it's a diagnosis of symptoms,</p> <p>19 basically. Pain with bladder filling,</p> <p>20 urgency, frequency. She doesn't really have</p> <p>21 as much urgency/frequency now, so it's a</p> <p>22 diagnosis that I would kind of watch a</p> <p>23 patient and see, maybe try some local</p> <p>24 treatments with some bladder instillations to</p>

Christina Pramudji, M.D.

<p style="text-align: right;">Page 213</p> <p>1 calm down the bladder with local anesthetic; 2 something, you know, not too invasive to try 3 to see if that gives her relief. 4 But that said, you know, if she 5 does have interstitial cystitis, that would 6 definitely cause this chronic pelvic pain, 7 that deep central pain that she's described 8 to me and to others, and oftentimes, that 9 goes hand-in-hand with levator spasm, where 10 they both kind of interplay with each other. 11 Q. Okay. So let me -- so there's 12 pain when her bladder fills, but that's 13 different than the tenderness between her 14 urethra and her vagina and that's different 15 than the muscle spasm, correct? 16 A. Correct. 17 Q. And that's kind of what we talked 18 about before when women can tell the 19 difference, for example, between a urinary 20 tract infection and menstrual cramps. 21 A. Right. 22 Q. So that's a separate identifiable 23 source of pain for her, correct? 24 A. Yes.</p>	<p style="text-align: right;">Page 214</p> <p>1 Q. And I think, if I'm remembering 2 correctly, that that interstitial cystitis 3 can be exacerbated by pelvic surgery. Is 4 that right, the symptoms of it? 5 A. Yes, it can be. Uh-huh. 6 Q. Okay. So then the pelvic surgery 7 that would be relevant to Mrs. Huskey's case 8 would be two different kinds of surgeries, 9 both the implant of the TVT-O device and the 10 explant of the TVT-O device, correct, those 11 two separate surgeries? 12 A. Yes. 13 Q. So those two separate surgeries 14 could be a contributing cause of the symptoms 15 that she experiences from the underlying 16 interstitial cystitis? 17 A. It could be. 18 Q. If that's what, indeed, she has? 19 A. Right. 20 Q. Okay. And you're making that 21 diagnosis based on you believe that that's a 22 possibility, but you can't definitively say 23 that she has it at this point. Is that 24 right?</p>
<p style="text-align: right;">Page 215</p> <p>1 A. Correct. 2 Q. Okay. Is there anything -- I 3 want to make sure that I have the whole list. 4 Is there anything else? 5 A. Well, scar tissue from 6 hysterectomy is always a possibility, 7 adhesions, but it doesn't sound like that to 8 me. That's all I can think of. 9 Q. So in this case, even though it's 10 a possibility, it does seem unlikely? 11 A. It's kind of further down the 12 differential diagnosis. 13 Q. Okay. So then let's go back to 14 talking about the new type of pain that she 15 experienced. And you're not suggesting that 16 the use of the speculum during the pelvic 17 exam caused some kind of damage or caused 18 some kind of muscle spasm or tenderness in 19 the vagina, correct? 20 A. I don't think it caused it. 21 Somehow it triggered that muscle to go into 22 spasm. I don't know if it was her -- I don't 23 know. I don't know how that happened. 24 Q. Okay. And so you agree with me,</p>	<p style="text-align: right;">Page 216</p> <p>1 from reading her medical records, that 2 between the explant surgery and that 3 follow-up visit, nothing else had been in 4 Mrs. Huskey's vagina, correct? 5 A. Correct. 6 Q. She had not had intercourse with 7 her husband during that time, so it was 8 really the first time that anything was 9 introduced into her vagina following the 10 explant surgery, that triggered both the 11 muscle spasm and the other point tenderness 12 that we discussed, correct? 13 A. As far as we know. 14 Q. Okay. And will you agree with me 15 that that all -- one of the causes of that 16 could be the pelvic surgery to remove the 17 TVT-O device itself? 18 MR. SNELL: Form. 19 A. I don't think so, because it's in 20 a different compartment. I mean, I suppose, 21 just speculating, just with any surgery in 22 that area, you know, maybe there could be a 23 reaction there with the muscle. But it's so 24 far away from it, I just feel like that's</p>

54 (Pages 213 to 216)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 217</p> <p>1 very unlikely, in my opinion. 2 BY MS. KIRKPATRICK: 3 Q. I think that we had -- so you 4 have no explanation for why all of these 5 other conditions which are -- you'll agree 6 with me, are more distal in time to the 7 explant surgery, correct? They all predated 8 the explant surgery? 9 MR. SNELL: Form. Form. 10 A. What all? 11 BY MS. KIRKPATRICK: 12 Q. All of the other issues that we 13 talked about. For example, she had SI joint 14 issues before she had the removal surgery, 15 correct? 16 A. Uh-huh. 17 Q. And she had -- 18 MR. SNELL: Hold on. You have to 19 say yes or no. It comes out uh-huh, 20 huh-uh. 21 THE WITNESS: Yes. Sorry. Yes. 22 BY MS. KIRKPATRICK: 23 Q. I'll go back so we have a clean 24 record on that.</p>	<p style="text-align: right;">Page 218</p> <p>1 You'll agree with me that the SI 2 joint issues predated the surgery to remove 3 the TVT-O stress, correct? 4 A. Yes. 5 Q. And you'll agree with me that she 6 had stress that existed before she had the 7 removal surgery to take out the TVT-O mesh, 8 correct? 9 A. Yes. 10 Q. And you'll agree with me that 11 these bladder issues, to the extent they 12 existed, predated the removal of the TVT-O 13 mesh, correct? 14 A. Yes. 15 Q. Yet the pain itself didn't 16 express itself until after the surgery. 17 A. Yes. 18 Q. Okay. But you don't think that 19 the surgery, even though it was the closest 20 thing in time, was the cause of the problems 21 that she's having? 22 A. No. 23 Q. And you don't think it's a cause 24 of -- in conjunction with the rest of the</p>
<p style="text-align: right;">Page 219</p> <p>1 issues that she had to the problem? 2 A. No. I think it's way down the 3 list as a possible cause. 4 Q. So it's just a coincidence? 5 A. I think so. I think it's a 6 confluence of factors, and, you know, she had 7 been -- Dr. Siddique had planted in her head 8 that she was going to have dyspareunia and 9 chronic pelvic pain and chronic problems, and 10 I think that, you know, all that contributed 11 to, and all the other factors that she had 12 could have all contributed to make it happen. 13 But I don't know why making an 14 anterior incision in the vaginal wall, 15 removing the piece of mesh, and then she felt 16 great afterwards, I don't know why that would 17 cause a spasm six weeks later. That's kind 18 of farfetched. 19 Q. Okay. What do you mean, "planted 20 in her head"? 21 A. Well, when she first saw him, he 22 said that, "Well, I need to remove all the 23 mesh but you may still have dyspareunia, you 24 will -- you may have chronic pain and</p>	<p style="text-align: right;">Page 220</p> <p>1 recurrent incontinence," and, you know, 2 she -- up till that point, she had some pain, 3 she had dyspareunia, but that was just the 4 mesh exposure. And I think he kind of 5 sensitized her to that. 6 Q. You're not suggesting, are you, 7 that Mrs. Huskey's current medical conditions 8 are all in her head, are you? 9 A. No. Absolutely not. 10 Q. And they are clinically 11 documented through your exam and through her 12 medical records, correct? 13 A. Absolutely. 14 Q. And you're not suggesting that 15 Mrs. Huskey is willing herself to have such 16 bad chronic pelvic pain that she can't have 17 sex with her husband, are you? 18 MR. SNELL: Form. 19 A. No. But you know that we're not 20 just a body and a mind, it's all 21 interconnected. And so if there's a -- if 22 you're told that you're not going to get 23 better, then you may not get better. If 24 you're told that you're optimistic and that</p>

55 (Pages 217 to 220)

Page 221	Page 222
<p>1 you're going to get better, then you have a</p> <p>2 better chance of getting better. It depends</p> <p>3 on your outlook, and doctors see this all the</p> <p>4 time, how patients' outlook on things will</p> <p>5 improve they're outcome.</p> <p>6 And so I'm not saying that I'm</p> <p>7 not -- I don't know if that's what's going on</p> <p>8 here, but it could be part of it. And I</p> <p>9 think that she's got a lot of stress and</p> <p>10 depression that I don't know is adequately</p> <p>11 treated, and that is known to exacerbate</p> <p>12 chronic pain and muscle spasm, not just in</p> <p>13 the pelvic floor but in other parts of the</p> <p>14 body. Chronic back pain, we talked about</p> <p>15 migraines.</p> <p>16 So all that is interconnected.</p> <p>17 And as a source of the spasm, I don't know if</p> <p>18 it was, but I think it can definitely</p> <p>19 exacerbate it and I see that clinically in</p> <p>20 practice. Anyone that deals with pelvic pain</p> <p>21 will see patients come in with pelvic floor</p> <p>22 spasm that's made worse by stress.</p> <p>23 And all the stress that she's</p> <p>24 been under with this lawsuit and with her</p>	<p>1 breast cancer, I know that's all contributing</p> <p>2 and making it harder for her. I'm not saying</p> <p>3 that that caused it and I'm certainly not</p> <p>4 saying that that's in her head.</p> <p>5 BY MS. KIRKPATRICK:</p> <p>6 Q. Okay. Well, let me go back to</p> <p>7 that.</p> <p>8 This muscle spasm occurred before</p> <p>9 she was involved in any lawsuit, correct?</p> <p>10 A. I don't know when she filed the</p> <p>11 lawsuit, but I know it's after she saw the</p> <p>12 commercials and asked Dr. Byrkit about the</p> <p>13 mesh lawsuits. So she had been -- it was on</p> <p>14 her radar.</p> <p>15 Q. Okay. You'll agree with me,</p> <p>16 though, that if the reports of the muscle</p> <p>17 spasm and the problems predated that, that</p> <p>18 there's no correlation; you're not</p> <p>19 suggesting, are you, that Mrs. Huskey is</p> <p>20 making up any of this for the purposes of a</p> <p>21 lawsuit?</p> <p>22 MR. SNELL: Hold on. Hold on,</p> <p>23 hold on. Form and foundation.</p> <p>24 Go ahead.</p>
Page 223	Page 224
<p>1 A. I'm not suggesting she's making</p> <p>2 it up, no. She definitely has a muscle spasm</p> <p>3 there.</p> <p>4 BY MS. KIRKPATRICK:</p> <p>5 Q. Okay. And you can't fake a</p> <p>6 muscle spasm, correct?</p> <p>7 A. No.</p> <p>8 Q. And Mrs. Huskey is not faking a</p> <p>9 muscle spasm?</p> <p>10 A. No.</p> <p>11 Q. Okay. So something is causing</p> <p>12 the muscle spasm that she is having, correct?</p> <p>13 A. Yes.</p> <p>14 Q. And she's also not faking the</p> <p>15 point tenderness between the urethra and the</p> <p>16 vagina, correct?</p> <p>17 A. I have to take her word for that.</p> <p>18 I mean, pain on examination, tenderness, you</p> <p>19 just have to take the patient's word for it.</p> <p>20 Q. Okay. Do you have any reason to</p> <p>21 doubt her word for it?</p> <p>22 A. No. I think she was -- I think</p> <p>23 she was legitimate on that.</p> <p>24 Q. You believe that she was being</p>	<p>1 honest with you in what she was telling you</p> <p>2 during the exam, correct?</p> <p>3 A. As far as I could tell, yeah.</p> <p>4 Q. Okay. You have no reason to</p> <p>5 suspect that.</p> <p>6 And in addition to that, you're</p> <p>7 not suggesting in any way that Mrs. Huskey</p> <p>8 had her sling removed for the purposes of any</p> <p>9 kind of lawsuit, are you?</p> <p>10 MR. SNELL: Form.</p> <p>11 A. No.</p> <p>12 BY MS. KIRKPATRICK:</p> <p>13 Q. And she had it removed because</p> <p>14 that was, in her doctor's estimation, what</p> <p>15 was necessary to relieve the physical</p> <p>16 symptoms that she was having, correct?</p> <p>17 A. Correct.</p> <p>18 Q. And you don't second-guess that</p> <p>19 opinion at all, do you?</p> <p>20 A. No. I don't know if I would have</p> <p>21 done as extensive of an excision. I don't</p> <p>22 think she needed to have the whole thing</p> <p>23 removed. He could have left the part on the</p> <p>24 other side and she might have maintained</p>

<p style="text-align: right;">Page 225</p> <p>1 continence if he had left that in place. 2 She was only complaining of the 3 area where there was an exposure. 4 Q. But you're not second-guessing 5 his medical judgment in performing the 6 surgery on Mrs. Huskey, correct? 7 A. Right. I mean, medicine is a 8 practice, so we have different opinions at 9 different times. He saw the patient at that 10 time. That's what he thought. But from what 11 I read, it sounded like he could have just 12 removed that area, that one area. 13 Q. But you haven't spoken to him 14 about the case, correct? 15 A. I've read his deposition, but 16 that's all. 17 Q. Right. But you haven't spoken to 18 him? 19 A. And the medical record. No. 20 Q. And you weren't there at the time 21 to see what she was like on examination when 22 he saw her? 23 MR. SNELL: Form. 24 A. Right.</p>	<p style="text-align: right;">Page 226</p> <p>1 BY MS. KIRKPATRICK: 2 Q. And you don't have a reason to 3 second-guess that medical judgment? 4 MR. SNELL: Form. 5 Go ahead. 6 A. Well, he didn't -- there was no 7 point, there was no record of tenderness on 8 the contralateral side, so -- 9 BY MS. KIRKPATRICK: 10 Q. What's the contralateral side? 11 Can you show me on that drawing? 12 A. Just the other side from where 13 the mesh exposure was. She had the mesh 14 exposure here on the right within the vaginal 15 wall, so -- was it the right or the left, I 16 get confused -- but on the other side, at 17 that time she didn't have tenderness. 18 MR. SNELL: If you need to look 19 at the records, feel free to look at the 20 records. 21 BY MS. KIRKPATRICK: 22 Q. Yeah, you can absolutely feel 23 free to look at the records if you want to. 24 (Witness reviews document(s).)</p>
<p style="text-align: right;">Page 227</p> <p>1 A. On the right. So he noted a 2 2-centimeter mesh exposure on the right 3 sulcus, and rather than just removing that 4 whole area, he removed the whole thing. 5 BY MS. KIRKPATRICK: 6 Q. Okay. But that wasn't for 7 purposes of litigation, correct? 8 A. Correct. 9 Q. And can -- I think we talked 10 about this before, but just let me make sure. 11 The mesh is a foreign body that's implanted 12 in Ms. Huskey's pelvis, correct? 13 A. Correct. 14 Q. And anytime you implant a foreign 15 body into someone, it can cause a chronic 16 inflammatory reaction, correct? 17 A. It's a nerve, so it causes a mild 18 chronic inflammatory reaction. It's not 19 significant. 20 Q. You believe that's not 21 significant? 22 A. No. 23 Q. What's that based on? 24 A. Based on experience and on the</p>	<p style="text-align: right;">Page 228</p> <p>1 literature. 2 Q. What literature? 3 A. The whole body of literature. 4 There's not -- hasn't been problems with 5 chronic inflammation in slings. 6 Q. Okay. So your opinion is that a 7 sling cannot cause a chronic inflammatory 8 response in a person? 9 A. No. 10 Q. Is that right? 11 A. That's not my opinion. 12 Q. Oh, okay. Can you tell me what 13 your opinion is? 14 A. I said it can cause a mild 15 chronic inflammatory response but nothing 16 that's clinically significant. 17 Q. Do you believe that an 18 inflammatory response in connection with scar 19 tissue in the pelvis can cause pain upon 20 bladder filling? 21 A. Repeat that question, please? 22 Q. Okay. Do you believe if the 23 pelvis is both inflamed and has scar tissue 24 in it, that that can cause pain upon bladder</p>

Christina Pramudji, M.D.

Page 229	Page 230
<p>1 filling?</p> <p>2 A. Just anywhere in the pelvis?</p> <p>3 Q. Anywhere in the pelvis. Well, I</p> <p>4 mean, let's -- you know, where the TVT-O is</p> <p>5 placed.</p> <p>6 MR. SNELL: Form.</p> <p>7 Go ahead.</p> <p>8 A. I would think it unlikely.</p> <p>9 BY MS. KIRKPATRICK:</p> <p>10 Q. Around the urethra and bladder?</p> <p>11 A. It's unlikely.</p> <p>12 Q. You think that's unlikely too.</p> <p>13 A. Yeah.</p> <p>14 Q. Okay. Now, you'll agree with me,</p> <p>15 though, that Mrs. Huskey has had a number of</p> <p>16 cystoscopies, correct?</p> <p>17 A. Yes.</p> <p>18 Q. And she's never been diagnosed</p> <p>19 with interstitial cystitis?</p> <p>20 A. Well, it's not a diagnosis that</p> <p>21 you would make on a regular cystoscopy.</p> <p>22 Q. She's never been diagnosed, has</p> <p>23 she?</p> <p>24 A. No.</p>	<p>1 Q. Okay.</p> <p>2 A. You would have to do a</p> <p>3 hydrodistention, and even that's not</p> <p>4 100 percent specific. Like I said, it's</p> <p>5 diagnosed based on symptoms and ruling out</p> <p>6 other disease processes.</p> <p>7 Q. I want to talk about the speculum</p> <p>8 exam. Do you perform speculum exams?</p> <p>9 A. Yes.</p> <p>10 Q. About how many have you performed</p> <p>11 over the course of your medical career?</p> <p>12 A. Thousands upon thousands.</p> <p>13 Q. And in those thousands upon</p> <p>14 thousands of speculum exams that you've done,</p> <p>15 have you ever seen a situation in which a</p> <p>16 speculum exam triggered the type of levator</p> <p>17 muscle spasm that Mrs. Huskey is having?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. When did you see that?</p> <p>20 A. I've seen patients that would</p> <p>21 have severe pain afterwards and they had a</p> <p>22 muscle spasm.</p> <p>23 Q. Okay. Severe chronic pain</p> <p>24 afterwards?</p>
Page 231	Page 232
<p>1 A. Uh-huh.</p> <p>2 Q. And it never went away?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. How many patients like</p> <p>5 that have you seen?</p> <p>6 A. Just a couple.</p> <p>7 Q. Okay. And what do you believe</p> <p>8 caused their spasms?</p> <p>9 A. Anxiety about the exam. I don't</p> <p>10 know, chronic tenderness in the area. These</p> <p>11 are chronic pelvic pain patients.</p> <p>12 Q. Okay. So you've seen that in</p> <p>13 about two of thousands of women, right?</p> <p>14 A. Correct, uh-huh.</p> <p>15 Q. Okay. Have you ever seen any</p> <p>16 reports in the medical literature or anything</p> <p>17 discussing why a speculum exam would trigger</p> <p>18 a levator muscle spasm?</p> <p>19 A. I've never seen anything like</p> <p>20 that.</p> <p>21 Q. So it's just a couple of patients</p> <p>22 that you've seen have -- when did you see</p> <p>23 those patients?</p> <p>24 A. I don't know. Years ago. I</p>	<p>1 don't remember.</p> <p>2 Q. Have you seen anyone have that</p> <p>3 reaction in the last five years?</p> <p>4 A. I don't recall.</p> <p>5 Q. In the last 10 years?</p> <p>6 A. I don't know when it was, but</p> <p>7 I've seen it happen before.</p> <p>8 Q. Can you give me a ballpark of</p> <p>9 when you saw that?</p> <p>10 A. Maybe three or four years ago.</p> <p>11 Q. Did either of those patients have</p> <p>12 mesh?</p> <p>13 A. No.</p> <p>14 Q. Do you agree with me that the</p> <p>15 TVT-O sling was the cause of the mesh erosion</p> <p>16 that was seen by both Dr. Byrkit and</p> <p>17 Dr. Siddique?</p> <p>18 MR. SNELL: Form.</p> <p>19 A. The sling was the cause of the</p> <p>20 mesh erosion?</p> <p>21 BY MS. KIRKPATRICK:</p> <p>22 Q. There's no other cause of it, the</p> <p>23 sling is the cause of the erosion?</p> <p>24 MR. SNELL: Form.</p>

58 (Pages 229 to 232)

<p style="text-align: right;">Page 233</p> <p>1 Go ahead.</p> <p>2 A. And the sling was what was</p> <p>3 exposed. Whether it was the cause of it, I</p> <p>4 mean, it could have been the bleeding that</p> <p>5 she had right after the surgery, after she</p> <p>6 exerted herself and then she immediately had</p> <p>7 some significant bleeding, and it could have</p> <p>8 opened up the wound and then allowed the mesh</p> <p>9 to be exposed at that point.</p> <p>10 BY MS. KIRKPATRICK:</p> <p>11 Q. Okay. How many patients have you</p> <p>12 seen of the thousands that you have treated</p> <p>13 who had complications from their slings</p> <p>14 because they vacuumed?</p> <p>15 A. Have I seen that... probably two.</p> <p>16 Q. Two?</p> <p>17 A. Uh-huh.</p> <p>18 Q. Okay. And what kind of sling did</p> <p>19 they have?</p> <p>20 A. I don't remember.</p> <p>21 Q. Do you remember whether it was a</p> <p>22 transobturator or retropubic?</p> <p>23 A. No.</p> <p>24 Q. And what did you have to do after</p>	<p style="text-align: right;">Page 234</p> <p>1 they vacuumed?</p> <p>2 A. I can't remember the specifics of</p> <p>3 the case, but I can remember patients</p> <p>4 having -- coming in with problems after</p> <p>5 vacuuming. I can't remember if it was</p> <p>6 recurrence of incontinence or a mesh</p> <p>7 exposure. But I can think of specific cases</p> <p>8 where they were vacuuming and then they had</p> <p>9 problems.</p> <p>10 Q. Now, I want to go back to this</p> <p>11 drawing again. Now, we've -- I want to make</p> <p>12 sure I'm pointing at the right place. These</p> <p>13 are the muscles and these muscles, like every</p> <p>14 muscle in the body, operate by contracting,</p> <p>15 correct?</p> <p>16 A. Relaxing and contracting.</p> <p>17 Q. Relaxing and contracting.</p> <p>18 A. Yes.</p> <p>19 Q. And they're attached here to the</p> <p>20 obturator fascia, correct?</p> <p>21 A. No, to the arcus tendineus.</p> <p>22 Q. Which is at the edge of that,</p> <p>23 correct?</p> <p>24 A. Correct.</p>
<p style="text-align: right;">Page 235</p> <p>1 Q. And so as this muscle or any of</p> <p>2 these levator muscles contract, they</p> <p>3 necessarily will have an effect on what you</p> <p>4 just called it that I can't quite remember.</p> <p>5 A. The arcus tendineus.</p> <p>6 Q. Arcus tendineus.</p> <p>7 A. Well, the arcus tendineus is</p> <p>8 pretty well fixed, so it's designed to be</p> <p>9 there almost like a wall so that it</p> <p>10 doesn't -- it doesn't move when the muscles</p> <p>11 contract.</p> <p>12 Q. So how do the muscles contract if</p> <p>13 they're fixed in place?</p> <p>14 A. Well, it's just like a muscle</p> <p>15 that's fixed to the bones. The bones don't</p> <p>16 move but the muscle contracts, so it's the</p> <p>17 same thing with that arcus tendineus. It's</p> <p>18 designed to be the fixed point and then the</p> <p>19 muscles squeeze and the other organs move and</p> <p>20 the pelvic floor lifts.</p> <p>21 Q. So the other muscles there would</p> <p>22 be --</p> <p>23 A. The pelvic floor lifts or</p> <p>24 descends.</p>	<p style="text-align: right;">Page 236</p> <p>1 Q. The others would be the urethra,</p> <p>2 the vagina, the rectum, would all move in</p> <p>3 relation to the contraction of these</p> <p>4 particular muscles. Is that correct?</p> <p>5 A. Yes.</p> <p>6 Q. Okay.</p> <p>7 A. When you do your Kegels, you</p> <p>8 know, you'll feel the vagina squeezing around</p> <p>9 the -- on exam. And this is a 3D rendering.</p> <p>10 Of course -- well, it's 2D, but in 3D you've</p> <p>11 got the pelvic floor here, it's like a bowl,</p> <p>12 and then the arcus tendineus on the side and</p> <p>13 then the obturator fascia is like this.</p> <p>14 So these may extend, but this</p> <p>15 doesn't move. It's not -- even though</p> <p>16 they're right next to each other, they're not</p> <p>17 interconnected. The obturator is a</p> <p>18 completely different compartment, even though</p> <p>19 they're right there. This is moving but this</p> <p>20 is not moving in relationship to it</p> <p>21 (demonstrating).</p> <p>22 Q. So I think that you drew a</p> <p>23 picture of -- or I drew -- no, you drew the</p> <p>24 picture of the sling. I labeled it.</p>

Christina Pramudji, M.D.

<p style="text-align: right;">Page 237</p> <p>1 Can you tell me what muscles a 2 transobturator sling goes through, if any, 3 when it's placed? 4 MR. SNELL: Form. 5 A. I'd have to look at the anatomy 6 book because I don't have them memorized. 7 There's four or five muscles there. 8 BY MS. KIRKPATRICK: 9 Q. And the sling is placed through 10 those muscles, correct? 11 A. Uh-huh. 12 Q. And is it also placed through the 13 obturator fascia? 14 A. Yes. 15 Q. Okay. And then where does it 16 insert into the obturator space? 17 A. It's on the medial superior 18 aspect of the obturator foramen. 19 Q. Okay. And we've noted the 20 obturator foramen on this picture, correct? 21 A. I'm sorry, the obturator -- this 22 is the obturator canal. The obturator 23 foramen is the opening in the bone, so the 24 sling comes through right here and then the</p>	<p style="text-align: right;">Page 238</p> <p>1 obturator canal is over here. 2 Q. Okay. So this would be the 3 obturator canal -- 4 A. The obturator canal, yes. 5 Q. -- not the obturator foramen? 6 A. Yes. 7 Q. Okay. So it goes through the 8 obturator foramen into the obturator space, 9 correct? 10 A. Well, there's really no obturator 11 space. 12 Q. Okay. I thought you just told me 13 that the obturator space was different than 14 the muscles. 15 A. Well, it's a different muscle 16 compartment. 17 Q. Okay. What's the difference -- 18 okay. Compartment, it's the obturator 19 compartment. 20 A. When I was referring to the 21 pelvic floor, is that what you're talking 22 about? 23 Q. Yeah, I'm just trying to make 24 sure we have the same terms.</p>
<p style="text-align: right;">Page 239</p> <p>1 A. It's a compartment. 2 Q. Okay. The obturator compartment 3 is different than the pelvic floor 4 compartment? 5 A. Correct. 6 Q. But the transobturator sling goes 7 through the pelvic floor muscles and the 8 pelvic floor compartment, correct? 9 MR. SNELL: Form. 10 A. I mean, it might go through a 11 little bit of the muscles here, there's not 12 much there, before it gets to the obturator. 13 These are kind of below where the sling would 14 be, and then it would go through the 15 obturator. 16 BY MS. KIRKPATRICK: 17 Q. Into the obturator compartment, 18 is that right? 19 A. Canal, compartment, yeah. 20 Q. Okay. And you don't believe -- 21 it's your opinion that a transobturator sling 22 cannot cause a levator muscle spasm? 23 A. Not in that area. If anything, 24 it would be up in here, right next to the</p>	<p style="text-align: right;">Page 240</p> <p>1 urethra. 2 Q. So it has to be direct -- in your 3 opinion, it has to be directly adjacent to or 4 intertwined with the sling itself; otherwise 5 it cannot be a cause? 6 A. Yeah. I don't think so. It's 7 really far apart. You can't tell in this 8 picture, but they're very far apart from each 9 other. 10 Q. What do you mean by very -- how 11 much is very far? 12 A. I mean, this far apart. That's 13 very far apart (demonstrating). 14 Q. Well, can you give me an estimate 15 of what that is? 16 A. 3 centimeters. 17 Q. Maybe 3 centimeters apart? 18 A. Yeah, uh-huh. 19 Q. So you think there's 20 3 centimeters difference between where the 21 sling would have been implanted and where 22 she's having a muscle spasm? 23 A. Correct. 24 Q. Okay.</p>

60 (Pages 237 to 240)

<p style="text-align: right;">Page 241</p> <p>1 MR. SNELL: When we get to a good 2 stopping point, can you just let me know? 3 Because I've just got to go grab my bags. 4 MS. KIRKPATRICK: Oh, go grab 5 your stuff, yeah. 6 (Recess, 3:36 p.m. to 3:52 p.m.) 7 BY MS. KIRKPATRICK: 8 Q. Okay, Dr. Pramudji. In your 9 first report, you had notated that -- or 10 observed that you believe that Ms. Huskey 11 would need further therapy and medication for 12 her pelvic pain and dyspareunia. 13 Do you still hold that opinion? 14 A. Yes. 15 Q. And you said that overall, her 16 prognosis was good. 17 A. Yes. 18 Q. Do you still hold that opinion 19 after seeing her at the independent medical 20 exam? 21 A. Yes, I do. 22 Q. Would it surprise you to know 23 that after you performed a pelvic exam on 24 Mrs. Huskey, she had to be in a wheelchair?</p>	<p style="text-align: right;">Page 242</p> <p>1 A. Yeah, I would be surprised. 2 Q. And she had to be in a wheelchair 3 at the airport because of the severe pain 4 that she was in? 5 MR. SNELL: Object to form. 6 A. I mean, she has a spasm there. 7 She said it was tender on exam. I did a very 8 gentle exam. I'm surprised that it was that 9 bad. She didn't -- she walked out of the 10 office and didn't seem like she was in that 11 much pain. She was in some pain, but it 12 doesn't seem like it warranted a wheelchair. 13 BY MS. KIRKPATRICK: 14 Q. But you did know that she was in 15 pain when she walked out of the office after 16 the pelvic exam? 17 A. She said she was in tender, that 18 it had flared it up. 19 Q. And most women don't have pain 20 when they walk out of an office with a pelvic 21 exam, correct? 22 A. Correct. 23 Q. Now, in your second report, in 24 your IME, you phrased your prognosis a little</p>
<p style="text-align: right;">Page 243</p> <p>1 bit differently. 2 (Brief interruption.) 3 MR. SNELL: I'm sorry. Hold on. 4 BY MS. KIRKPATRICK: 5 Q. You noted that there are several 6 treatment options that can be explored but 7 there's hope for her to return to a 8 satisfying and productive life. 9 You would agree with me that 10 right now, her life is not particularly 11 satisfying, correct? 12 A. Well, she does have some leisure 13 activities that she participates in, but she 14 can't have intercourse with her husband right 15 now, which is important to her, and she says 16 that she can't work right now. 17 Q. Which is also something that's 18 very important to her, correct? 19 A. Uh-huh. 20 Q. And she can't exercise anymore, 21 correct? 22 A. That's what she says, yes. 23 Q. So her level of activity has 24 changed dramatically from what it was before</p>	<p style="text-align: right;">Page 244</p> <p>1 the TVT-O implant, correct? 2 MR. SNELL: Form. 3 A. As far as I can tell, yes. 4 BY MS. KIRKPATRICK: 5 Q. Okay. As far as what she 6 reports. 7 A. Yes. 8 Q. And there's nothing at all that 9 would make you question that, is there? 10 A. No. 11 Q. Okay. And she is in a loving 12 relationship, correct? 13 A. That's what she says, yes. 14 Q. Okay. And she also told you that 15 she does want to be able to have intercourse 16 with her husband, correct? 17 A. Yes. 18 Q. And she also told you that she 19 misses the ability to have physical intimacy 20 with her husband, correct? 21 A. I don't remember if she told me 22 that directly, but I know that's what the 23 records show. 24 Q. Okay. So you would agree with me</p>

Christina Pramudji, M.D.

Page 245

1 that it's not Mrs. Huskey's choice that she's
2 not able to have sex with her husband,
3 correct?

4 MR. SNELL: Form. Form.

5 A. I don't know for sure.

6 BY MS. KIRKPATRICK:

7 Q. You think she might be choosing
8 just not to have sex?

9 A. Some women will come up with
10 excuses. I don't know.

11 Q. Do you have any reason to
12 believe, based on what Mrs. Huskey has said
13 to you and what's in her medical records,
14 that she's making up excuses not to have sex
15 with her husband?

16 A. I don't know. I mean, I know
17 she's had some difficult relationships in the
18 past. I don't know her whole past. But from
19 what I can tell, no, she seems like she's
20 being straight about that.

21 Q. Okay. And you also talk about a
22 productive life. We talked about Mrs. Huskey
23 isn't able to work, correct?

24 A. Uh-huh. Yes. That's what she

Page 247

1 with Mrs. Huskey right now, is it?

2 A. I think that's obviously part of
3 it, that she's getting older as well. But
4 that's not the main part of it, no. I think
5 the main thing that's holding her back is the
6 levator muscle spasm.

7 Q. And the pain that that's causing
8 her, correct?

9 A. Correct.

10 Q. What do you mean, there's hope?

11 A. That if she has therapy and she
12 sticks with it, that she could have a good
13 prognosis, that that can be resolved.

14 Q. Okay. It could be resolved --

15 A. Yes.

16 Q. -- but it won't definitely be
17 resolved, correct?

18 MR. SNELL: Form.

19 A. There's no definite in medicine.

20 BY MS. KIRKPATRICK:

21 Q. Now, I want to ask you just a
22 couple of questions about your pelvic exam of
23 Mrs. Huskey.

24 A. Sure.

Page 246

1 says.

2 Q. And she's not able to engage in
3 many of the activities that she engaged in
4 both through work and through her personal
5 life, correct?

6 MR. SNELL: Form.

7 A. I know that she enjoys her boat
8 and she does a lot of gardening and work
9 around the house, so she's able to be fairly
10 active at times. I don't think it's as much
11 as she did before. It may be different. But
12 our lives change as we get older as well, so,
13 you know, I think that there's a lot that she
14 can still do.

15 BY MS. KIRKPATRICK:

16 Q. Okay. Do you think that any of
17 the changes in Mrs. Huskey's life have
18 occurred because she's gotten older between
19 the time of the TVT-O implant and six weeks
20 after the TVT-O explant?

21 A. Can you repeat that question?

22 Q. Sure. You said that things
23 change when we get older, our lives change as
24 we get older. That's not what's going on

Page 248

1 Q. First of all, let me ask you
2 this: You indicated that to Mrs. Huskey her
3 ability to have sexual relations with her
4 husband was important to her, correct?

5 A. Yes, and I believe she's sexually
6 intimate with him, but just not with
7 intercourse.

8 Q. Okay. But that intercourse is
9 important to her, correct?

10 A. We didn't talk about it
11 specifically.

12 Q. So you didn't ask her at the exam
13 about her ability to have intercourse?

14 A. I think we talked about, you
15 know, the intercourse that she had had over
16 time and that right now, it's uncomfortable,
17 but we didn't talk about how important it is
18 to her, which was your question.

19 Q. Did she say it was uncomfortable
20 or did she say it was painful?

21 A. She said it was painful at this
22 point.

23 Q. Okay. And did she tell you that
24 it caused her so much pain that at times it

<p style="text-align: right;">Page 249</p> <p>1 has caused her to cry?</p> <p>2 A. No.</p> <p>3 Q. Those are not normal reactions to</p> <p>4 intercourse, correct?</p> <p>5 A. Correct.</p> <p>6 Q. And that's not just something</p> <p>7 that you could attribute to a vaginal</p> <p>8 atrophy, correct?</p> <p>9 MR. SNELL: Form.</p> <p>10 A. There are a lot of women that</p> <p>11 have severe vaginal atrophy that will cause</p> <p>12 them to cry when they try to have</p> <p>13 intercourse.</p> <p>14 BY MS. KIRKPATRICK:</p> <p>15 Q. And that's solved when you give</p> <p>16 them generally a Premarin cream?</p> <p>17 A. Yes, over time. It takes time</p> <p>18 for it to be effective, and sometimes they</p> <p>19 need pelvic floor therapy and stretching of</p> <p>20 the tissues and more than just the cream.</p> <p>21 Q. Okay. But they would require</p> <p>22 treatment for that, correct?</p> <p>23 A. Yes.</p> <p>24 Q. You don't talk in your report</p>	<p style="text-align: right;">Page 250</p> <p>1 about sexual function for Mrs. Huskey. Why</p> <p>2 not?</p> <p>3 MR. SNELL: Form. Misstates.</p> <p>4 A. I do. Yeah, I talk about the</p> <p>5 discomfort that she has and the pain with</p> <p>6 stimulation.</p> <p>7 BY MS. KIRKPATRICK:</p> <p>8 Q. When you're talking about the</p> <p>9 limitations on her life and what it is --</p> <p>10 well, you know what, if --</p> <p>11 (Counsel reviewing realtime</p> <p>12 transcript on an iPad.)</p> <p>13 BY MS. KIRKPATRICK:</p> <p>14 Q. Show me where in your report you</p> <p>15 talk about her sexual functioning in your</p> <p>16 IME.</p> <p>17 A. You're talking about the IME?</p> <p>18 Q. Uh-huh.</p> <p>19 A. The second-to-last paragraph on</p> <p>20 page 1, when she had intercourse after the</p> <p>21 TVT, when she had the mesh exposure.</p> <p>22 Q. Okay. That's where you're</p> <p>23 reciting her medical history, correct?</p> <p>24 A. Correct. Is that what you were</p>
<p style="text-align: right;">Page 251</p> <p>1 referring to?</p> <p>2 Q. Yeah.</p> <p>3 A. And then on page 2, the second</p> <p>4 paragraph, when she had the -- after the</p> <p>5 explant, she had painful intercourse. The</p> <p>6 third paragraph, she was able to have sex</p> <p>7 successfully two times that it wasn't</p> <p>8 horrible, so it was tolerable, it's getting</p> <p>9 better, and that was when she was actively</p> <p>10 having physical therapy, which was why I feel</p> <p>11 like there's hope for her, because when she</p> <p>12 was having therapy and doing well on the</p> <p>13 Cymbalta, she was actually doing well or</p> <p>14 getting better. She got down to a pain level</p> <p>15 of 2 to 3, I believe.</p> <p>16 Q. Do you consider sex that's not</p> <p>17 horrible to be doing well?</p> <p>18 A. Getting better. She was getting</p> <p>19 better.</p> <p>20 Q. But it's not doing well, and</p> <p>21 that's certainly not the standard.</p> <p>22 A. No.</p> <p>23 Q. We wouldn't want to be aiming</p> <p>24 just to get her to a point that it's not</p>	<p style="text-align: right;">Page 252</p> <p>1 horrible, right?</p> <p>2 A. And I think -- that's what she</p> <p>3 told me. But I think in the medical records</p> <p>4 when it was closer to the event, that I read</p> <p>5 that it was not bad. I believe that was in</p> <p>6 Dr. Siddique's records.</p> <p>7 Q. Not a rousing endorsement either.</p> <p>8 A. But the point is, getting better</p> <p>9 with therapy. Not there, but improving.</p> <p>10 Q. Okay. And in your impressions,</p> <p>11 do you comment on her sexual function as</p> <p>12 sexual dysfunction?</p> <p>13 A. Not specifically, no, I don't.</p> <p>14 Q. So in the two -- well, page and a</p> <p>15 half that you devote to that, that wasn't</p> <p>16 something that you believed was important</p> <p>17 enough to note. Is that right?</p> <p>18 A. Well, I'm kind of -- in my mind,</p> <p>19 I was putting that in with the pelvic pain</p> <p>20 and the treatments for the pelvic pain and</p> <p>21 kind of putting that all together, even</p> <p>22 though I didn't specifically call it out.</p> <p>23 Q. Okay. And -- hang on one second.</p> <p>24 (Sotto voce discussion.)</p>

Christina Pramudji, M.D.

Page 253

1 MS. KIRKPATRICK: I think that's
2 all that I have.

3 EXAMINATION

4 BY MR. SNELL:

5 Q. Dr. Pramudji, Burt Snell. I have
6 some follow-up questions, and why don't we
7 kind of start where we left off, where
8 Mrs. Huskey is right now. You saw
9 Mrs. Huskey at the IME, correct?

10 A. Correct.

11 Q. You're aware that she has cancer,
12 correct?

13 A. Correct.

14 Q. Can that cancer obviously have an
15 effect on her well-being?

16 A. Yes.

17 Q. Can it have an effect on her
18 stress levels?

19 A. Absolutely.

20 Q. Can the treatment modalities for
21 cancer have an effect on her stress levels
22 and her well-being?

23 A. Yes, she was in acute pain from
24 the breast expanders on the day of the exam.

Page 255

1 Q. In your report on page 4, we were
2 just looking at the impression section of
3 your IME. It says "The levator pain that has
4 occurred since the mesh was explanted was
5 precipitated on speculum exam," and I believe
6 you discussed that part with plaintiff's
7 counsel, correct?

8 A. Correct.

9 Q. "And is a spasmodic pain at the
10 posterior wall of the introitus, well away
11 from the area of sling insertion."

12 Did I read that correctly?

13 A. That's correct.

14 Q. And I think you've testified to
15 that, you can correct me if I'm wrong or not.
16 But where her spasm and pain was is not in an
17 area where the sling was. Is that correct or
18 not?

19 A. Correct. It's too posterior to
20 be caused by the sling.

21 Q. And you state "This was not
22 caused by the sling and was precipitated on
23 speculum examination. The primary area of
24 muscle spasm and pain is too posterior to be

Page 254

1 She was very sensitized and almost tearful to
2 begin with.

3 Q. Plaintiff's counsel asked you
4 questions about Mrs. Huskey's claim that she
5 cannot work. Did you see any of the doctors,
6 her treating doctors, say that she could not
7 work because of her sling surgeries?

8 A. No.

9 Q. Do you believe she can't work
10 because of her sling surgeries?

11 A. No.

12 Q. Plaintiff's counsel asked you
13 about her ability to engage in leisure
14 activities. Do you think the sling had any
15 effect on her leisure abilities?

16 A. I don't think so. I mean, she's
17 been able to enjoy boating and gardening and
18 house projects.

19 Q. Mrs. Huskey claims that she can't
20 exercise or can't exercise as much. Do you
21 believe that the sling had any effect or
22 cause on that claim?

23 A. No. I think the muscle spasm is
24 what's affecting her.

Page 256

1 caused by the sling."

2 Did I read that correctly?

3 A. Yes.

4 Q. Is that an opinion you continue
5 to hold?

6 A. Yes.

7 Q. You hold that opinion to a
8 reasonable degree of medical certainty?

9 A. Yes.

10 Q. Plaintiff's counsel asked you
11 some questions about vacuuming and whether
12 vacuuming can lead to mesh exposure. And
13 there seemed to be some cynicism about how
14 strenuous vacuuming was.

15 My question is this: Did
16 Mrs. Huskey call in to her doctor 10 days
17 after her surgery and report that she was
18 having heavy bleeding?

19 A. Yes, she did.

20 Q. Did they ask her to come in and
21 be seen?

22 A. Yes.

23 Q. And was a mesh exposure seen at
24 that time?

Christina Pramudji, M.D.

Page 257	Page 258
<p>1 A. Yes.</p> <p>2 Q. Is a mesh exposure a wound</p> <p>3 complication?</p> <p>4 A. Yes.</p> <p>5 Q. Can wound complications occur</p> <p>6 with any surgery, any pelvic floor surgery?</p> <p>7 A. Yes. Any wound can break down.</p> <p>8 Q. And in your initial report, you</p> <p>9 state that you believe that she had general</p> <p>10 wound healing issues which led to her</p> <p>11 exposure. Is that correct or not?</p> <p>12 A. Yes, because of the mesh</p> <p>13 exposure, that would indicate that there was</p> <p>14 a problem with the wound healing, and I don't</p> <p>15 know how the buttonholing contributed to that</p> <p>16 or not, and then the heavy bleeding</p> <p>17 definitely, because that had to come out</p> <p>18 somewhere. It would come out of the wound,</p> <p>19 more than likely.</p> <p>20 Q. Okay. Plaintiff's counsel --</p> <p>21 strike that.</p> <p>22 There was some testimony about</p> <p>23 endometriosis. Do you recall that?</p> <p>24 A. Yes.</p>	<p>1 Q. Is endometriosis common?</p> <p>2 A. Yes.</p> <p>3 Q. Has anybody ruled out</p> <p>4 endometriosis as a cause of Mrs. Huskey's</p> <p>5 pain, in your opinion?</p> <p>6 A. No.</p> <p>7 Q. Do you have Dr. Steege's</p> <p>8 deposition or deposition exhibits handy?</p> <p>9 A. Yes.</p> <p>10 Q. I believe plaintiff's counsel</p> <p>11 asked you about literature regarding how</p> <p>12 common endometriosis can be?</p> <p>13 MS. KIRKPATRICK: Objection.</p> <p>14 MR. SNELL: I know you did.</p> <p>15 MS. KIRKPATRICK: I know I</p> <p>16 didn't.</p> <p>17 BY MR. SNELL:</p> <p>18 Q. Do you remember a doctor</p> <p>19 testifying that endometriosis is commonly</p> <p>20 seen in women with pelvic pain?</p> <p>21 A. Yes.</p> <p>22 Q. All right. Is that opinion based</p> <p>23 on the literature, your clinical experience,</p> <p>24 one or both?</p>
Page 259	Page 260
<p>1 A. Both.</p> <p>2 Q. Looking at Exhibit 7 to</p> <p>3 Dr. Steege's dep, it's actually an ACOG</p> <p>4 Technical Bulletin on chronic pelvic pain,</p> <p>5 and on the subject of endometriosis, it</p> <p>6 states, "It has been found in up to 48% of</p> <p>7 women having laparoscope for evaluation of</p> <p>8 chronic pelvic pain."</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. What does that mean, in those</p> <p>12 women who presented with chronic pelvic pain</p> <p>13 who actually have a laparoscopic surgery,</p> <p>14 endometriosis was found in 48 percent?</p> <p>15 What's the significance of that opinion?</p> <p>16 A. That that's very common in anyone</p> <p>17 with pelvic pain, that you need to do</p> <p>18 laparoscopy to diagnose it.</p> <p>19 MS. KIRKPATRICK: Can I just see</p> <p>20 that before you put it away?</p> <p>21 THE WITNESS: Yeah.</p> <p>22 MS. KIRKPATRICK: Thanks.</p> <p>23 BY MR. SNELL:</p> <p>24 Q. Do you believe her back pain --</p>	<p>1 strike that.</p> <p>2 Has her back pain been ruled out</p> <p>3 as a cause of her pain?</p> <p>4 A. I don't think it's been</p> <p>5 completely ruled out, no.</p> <p>6 Q. There was some earlier questions</p> <p>7 about TVT-O and its placement and questions</p> <p>8 about placement in the vaginal wall. Let me</p> <p>9 just make sure I understand this and ask you,</p> <p>10 is TVT-O placed in the vaginal wall or behind</p> <p>11 the vaginal wall?</p> <p>12 A. Behind the vaginal wall. You</p> <p>13 create a space between the urethra and the</p> <p>14 vaginal wall and place it in that space.</p> <p>15 Q. Okay. One of the exhibits</p> <p>16 plaintiff's counsel marked was Exhibit 9, the</p> <p>17 TVT-O IFU from 2005, and you were asked some</p> <p>18 questions about that, correct?</p> <p>19 A. Yes.</p> <p>20 Q. On the first page, I'll read it</p> <p>21 to you, it states, "It is not a comprehensive</p> <p>22 reference to surgical technique for</p> <p>23 correcting SUI (Stress Urinary Incontinence).</p> <p>24 The device should be used only by physicians</p>

65 (Pages 257 to 260)

Christina Pramudji, M.D.

Page 261

1 in the surgical management of stress urinary
2 incontinence and specifically in implanting
3 the Gynecare TVT Obturator device."

4 Have you seen that before in the
5 TVT-O IFU?

6 A. Yes.

7 Q. And when you earlier testified
8 that other than mesh exposure there were
9 overlapping complications, would these be
10 complications that surgeons would be aware of
11 via their medical training and schooling?

12 A. Yes, absolutely. Yes, we're
13 taught about complications of pelvic surgery
14 and other various procedures that are
15 specific to those procedures.

16 Q. Where it talks -- and plaintiff's
17 counsel pointed this out -- about how it
18 should be placed with care to avoid vessels,
19 nerves, discussed those nerves and other
20 parts, is it common surgical knowledge in the
21 types of surgeons who would be doing stress
22 urinary incontinence that damage to nerves
23 can lead to pain?

24 A. Yes.

Page 263

1 dyspareunia?

2 A. Some, but not as much at all. It
3 would be very manageable.

4 Q. You were asked questions about
5 the primary endpoint in a study. Is the
6 primary endpoint the point by which the study
7 is powered?

8 A. Yes.

9 Q. You've looked at a lot of
10 literature, metaanalyses, document reviews,
11 correct?

12 A. Correct.

13 Q. And did they assess complications
14 and report on them?

15 A. Yes, absolutely. They don't just
16 report the success rate; they go into the
17 complications.

18 Q. And did you consider the data on
19 efficacy and complications for the TVT
20 retropubic device to be important as well in
21 your assessment of the TVT-O data?

22 A. Yes, absolutely. The TVT-O is
23 just a minor modification.

24 MR. SNELL: That's all I have.

Page 262

1 Q. And is it common knowledge that
2 pain can be short-term or sometimes
3 permanent?

4 A. Yes. It's very common knowledge.

5 Q. Did you see whether or not
6 Dr. Byrkit relied on the IFU?

7 A. She did not.

8 Q. In response to one of your
9 questions, I think you were cut off when you
10 were talking about the --

11 MS. KIRKPATRICK: Objection.

12 BY MR. SNELL:

13 Q. -- the little piece of scar
14 tissue under the urethra, and I wrote you
15 stated, "If that was all she had."

16 You didn't finish the answer. My
17 question to you is, were you trying to
18 complete your answer or not?

19 A. What I was trying to say was that
20 if that was all -- the only problem that she
21 had, I don't think we would be here today. I
22 don't think it would be a big issue for her
23 at all.

24 Q. Do you think that would cause

Page 264

1 Thanks.

2 FURTHER EXAMINATION

3 BY MS. KIRKPATRICK:

4 Q. That's -- I just have a couple of
5 questions for you.

6 Does endometriosis cause levator
7 muscle spasm?

8 A. If it's severe enough, it can put
9 their pelvic floor into spasm.

10 Q. If it's severe enough?

11 A. Uh-huh.

12 Q. Don't you think that it would
13 have been diagnosed before it got severe
14 enough to get to a levator muscle spasm in
15 Mrs. Huskey?

16 A. Possibly.

17 Q. Endometriosis is not the cause of
18 her levator muscle spasm, is it?

19 A. I don't know.

20 Q. Okay. You know there's
21 absolutely no evidence in her medical record
22 whatsoever that she has endometriosis, don't
23 you?

24 A. Well, there's no -- no one has

66 (Pages 261 to 264)

Christina Pramudji, M.D.

Page 265

1 ruled it out, either, completely.

2 Q. And you don't think that the
3 visual examination of normal ovaries and the
4 removal of her uterus are sufficient to rule
5 out pretty conclusively that she doesn't have
6 endometriosis?

7 MR. SNELL: Form.

8 A. Did she have a vaginal or an
9 abdominal hysterectomy? I can't recall.

10 BY MS. KIRKPATRICK:

11 Q. Well, you tell me. You're the
12 doctor.

13 A. Let me get that, because just
14 looking at the ovaries alone doesn't rule it
15 out. You can have implants throughout the
16 pelvis.

17 MR. SNELL: Do you need Byrkit?

18 THE WITNESS: Yeah, I need
19 Byrkit. That's what I was looking for.

20 MS. KIRKPATRICK: Here, I'm going
21 to give you this one too, if you're
22 looking for that.

23 (Witness reviews document(s).)

24 THE WITNESS: So far everything

Page 266

1 just says hysterectomy.

2 BY MS. KIRKPATRICK:

3 Q. Okay.

4 A. I don't recall a lower abdominal
5 incision, so I think it was vaginal, so it
6 would be hard to see anything with a vaginal
7 hysterectomy.

8 Q. One other question. I think that
9 you were asked on redirect about the
10 proximity again, and I think we had talked a
11 little bit about that. You had talked about
12 3 centimeters. I just want the record to
13 reflect that when you talked about
14 3 centimeters, you held up two fingers,
15 correct?

16 A. Uh-huh.

17 Q. And the space from the top to the
18 bottom of those two fingers, that's what
19 you're talking about as the amount of
20 distance between them, correct?

21 A. Yeah, roughly.

22 MS. KIRKPATRICK: Roughly, okay.

23 Nothing else, thank you.

24 THE WITNESS: Okay.

Page 267

1 FURTHER EXAMINATION

2 BY MR. SNELL:

3 Q. And my follow-up is, do you
4 hold -- continue to hold all your opinions in
5 your reports and IMEs to a reasonable degree
6 of medical and scientific certainty?

7 A. Yes, I do.

8 MR. SNELL: Thanks.

9 THE WITNESS: All right.

10 (Deposition recessed at 4:18 p.m.)

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Page 268

1 CERTIFICATE

2
3 I, SUSAN PERRY MILLER, Registered
4 Diplomate Reporter, Certified Realtime
5 Reporter, Certified Court Reporter and Notary
6 Public, do hereby certify that prior to the
7 commencement of the examination, CHRISTINA
8 PRAMUDJI, M.D. was duly sworn by me to
9 testify to the truth, the whole truth and
10 nothing but the truth;

11 That pursuant to Rule 30 of the
12 Federal Rules of Civil Procedure, signature
13 of the witness was not reserved by the
14 witness or other party before the conclusion
15 of the deposition;

16 That the foregoing is a verbatim
17 transcript of the testimony as taken
18 stenographically by and before me at the
19 time, place and on the date hereinbefore set
20 forth, to the best of my ability.

21 I DO FURTHER CERTIFY that I am
22 neither a relative nor employee nor attorney
23 nor counsel of any of the parties to this
24 action, and that I am neither a relative nor
25 employee of such attorney or counsel, and
26 that I am not financially interested in the
27 action.

28
29 Susan Perry Miller
30 CSR-TX, CCR-LA, CSR-CA
31 Registered Diplomate Reporter
32 Certified Realtime Reporter
33 Certified Broadcast Captioner
34 NCRA Realtime Systems Administrator
35 Certified LiveNote™ Reporter
36 Notary Public, State of Texas
37 My Commission Expires 03/30/2016

38 Dated: 24th of April, 2014
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67 (Pages 265 to 268)

Christina Pramudji, M.D.

Page 269

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Christina Pramudji

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Email string re: Ultrapro vs Prolene Soft Mesh
Email string, top one from Gary Pruden to David Robinson, et al. re: article entitled :Vaginal repair with mesh no better than colporrhapy for pelvic organ prolapse.
ETH MESH 00082651- 654
ETH MESH 07903682-3683
ETH MESH 09268043-045
ETH.MESH.00000172 8/25/11 Email from Marie Hobson to Kevin Frost attaching registration list for call
ETH.MESH.00000173 8/25/11 Registration list for 8/25/11 call
ETH.MESH.00003895 to ETH.MESH.00003895 Continence Health and Pelvic Floor Advisory Board Opening Comments for Renee
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ETH.MESH.00125373 to ETH.MESH.00125373 Email string, top one from Tom Eagan to Erin Haggerty re: Dr. Sepulveda.
ETH.MESH.00127103 to ETH.MESH.00127103 Email from Greg prine to Scott Jones, Jonathan Meek re: Prosima Road Show; cc: Lesley Fronio and Kevin Mahar.
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ETH.MESH.00310205 to ETH.MESH.00310205 Product Quality Issue re: Prosima signed by Mark Yale.
ETH.MESH.00310206 to ETH.MESH.00310206 Letter from David Robinson re: decision to delay preceptor training activities for Prosima (not signed).
ETH.MESH.00316849-ETH.MESH.00316850
ETH.MESH.00318930 to ETH.MESH.00318930 (Draft) Letter from David Robinson re: delay in preceptor training activities for Prosima.
ETH.MESH.00318934 to ETH.MESH.00318934 Document entitled " Delay in Prosima Activities."
ETH.MESH.00329474 to ETH.MESH.00329509 Project Mint Design Review
ETH.MESH.00335084 to ETH.MESH.00335085 Email from Daniel Lamont to Sungyoon Rha, et al. re: Mint Functional Strategies.
ETH.MESH.00405513-514
ETH.MESH.00409158 to ETH.MESH.00335158 Letter from David Robinson re: decision to delay preceptor training activities for Prosima (signed).
ETH.MESH.00409158 to ETH.MESH.00409158 (Official) Letter from David Robinson re: delay in preceptor training activities for Prosima.
ETH.MESH.00418855 to ETH.MESH.00418856 Email string, top one from Andrew Meek to Jonathan Fernandez, et al. re: Prosima Preceptor Recommendation Form; cc: Kevin Frost, et al.
ETH.MESH.00424374 to ETH.MESH.00424375 Email string, top one from Jonanthan Fernandez ro Rhonda Peebles re: remaining 2010 labs; cc: Robert Zipfel.
ETH.MESH.00426441 to ETH.MESH.00426441 Email from Kevin Frost to Robert Zipfel, et al. re: Prosima 2-year slide deck; cc: Paul Parisi.
ETH.MESH.00455676 to ETH.MESH.00455677 Email from Allison London Brown to Ophelie Berthier, et al. re: Prosima Jan 2007 update; cc: Bob Roda, et al.
ETH.MESH.00467320 to ETH.MESH.00467320 Email string, top one from Andrew Meek to Bart Pattyson, Paul Parisi re: November Lab.
ETH.MESH.00495796 to ETH.MESH.00495798 Email string, top one from Jennifer Paradise to Melissa Doyle, et al. re: Prof Ed through Tele-Mentoring; cc: Paul Parisi, et al.
ETH.MESH.00510562 to ETH.MESH.00510563 Email string, top one from Kevin Frost to DL-ETHUSSO EWHU DMS, et al. re: 1st Prosima Virtual Round Table Tomorrow; cc: Matt Henderson, et al.
ETH.MESH.00516424- 427
ETH.MESH.00541708 to ETH.MESH.00541709 Document entitled "Notes from Competitive Ad Board."
ETH.MESH.00541873 to ETH.MESH.00541873 Chart listing Proposed Lab Scheduling for August 4th.

Production Materials

ETH.MESH.00541876 to ETH.MESH.00541878 Email string, top one from Bart Pattyson to David Robinson, et al. re: ICS/IUGA Cadaver Lab - Monday Aug 23.
ETH.MESH.00542347 to ETH.MESH.00542348 Calendar appointment re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones and Schlafstein.; created by Robert Zipfel.
ETH.MESH.00542463 to ETH.MESH.00542463 Powerpoint: Gynecare Prosima™ Pelvic Floor Repair System: 2-Year Clinical Data
ETH.MESH.00547021 to ETH.MESH.00547021 Ethicon Women's Health & Urology "Welcome Letter" to the EWH&U Pelvic Floor Repair Advisory Board Meeting.
ETH.MESH.00547036 to ETH.MESH.00547037 Email string, top one from Bart Pattyson to Jaime Sepulveda, et al re: Prosima (&Elevate) Advisory Board - Jan 8th - Baltimore; cc: Piet Hinoul, et al.
ETH.MESH.00573815 to ETH.MESH.00573815 Powerpoint: Two Year Clinical Outcomes after Prolapse Surgery with Non-Anchored Mesh & Vaginal Support Device (Gynecare Prosima* Pelvic Floor Repair System) June 2010.
ETH.MESH.00573860 to ETH.MESH.00573878 (Draft) Sayer, T., et al. "Medium-term Clinical Outcomes Following Surgical Repair for Vaginal Prolpase with Tension-free Mesh and Vaginal Support Device."
ETH.MESH.00575580 to ETH.MESH.00575581 Email string, top one from Jonathan Meek to Piet Hinoul, Colin Urquhart and Judi Gauld re: Prosima anterior compartment result.
ETH.MESH.00575634 to ETH.MESH.00575635 ICS 2009 Abstract Form. "Surgery for Pelvic Organ Prolapse Using Mesh Implants and a Vaginal Support Device: Analysis of Anatomic, Functional and Performance Outcomes from an International, Multicentre Study."
ETH.MESH.00578081 to ETH.MESH.00578083 Email string, top one from Piet Hinoul to Paan Hermansson re: Prosima Post launch communication.
ETH.MESH.00578550 to ETH.MESH.00578550 (Draft) Sayer, T., et al. "Two Year Clinical Outcomes after Prolapse Surgery with Non-Anchored Mesh and Vaginal Support Device."
ETH.MESH.00579296 to ETH.MESH.00579296 Powerpoint: Anatomic and Functional Outcomes of 2 Pelvic Floor Repair Systems Studied in Moderate and Severe Prolpase Patients.
ETH.MESH.00580588 to ETH.MESH.00580589 Email string, top one from Piet Hinoul to Paan Hermansson re: key message for Prosima launch
ETH.MESH.00592224 to ETH.MESH.00592229 E-mail chain from Jonathan Meek to otehrs in regards to Technical Feedback on Prosima
ETH.MESH.00594528 Email from Aaron Kirkemo to Piet Hinoul, David Robinson and Judi Gauld re: Prosima commerical claims of 92.3% above the hymen.
ETH.MESH.00595468 to ETH.MESH.00595470 Goldman, H., FitzGerald, M. "Opposing Views: Transvaginal Mesh for Cystocele Repair," J Urol (2010) 183:430-432.
ETH.MESH.00595889 to ETH.MESH.00595890 Email string, top one from Kevin Frost to Aaron Kirkemo re: Prosima presentation; cc: Tom Affeld.
ETH.MESH.00604183 to ETH.MESH.00604186 Email string, top one from Piet Hinoul to Judi Gauld and Colin Urquhart re: PISQ, and score when unable to have sex.
ETH.MESH.00631782 to ETH.MESH.00631784 FDA Letter re: K063562 Gynecare Prosima
ETH.MESH.00679637 to ETH.MESH.00679640 Email string, top one from Zenobia Walji to Ron Naughton, et al. re: Prolene Soft Mesh '05 proposed pricing; cc: Kevin Maher, et al.
ETH.MESH.00759327 to ETH.MESH.00759335 Document entitled "Experience what's new in incontinence and pelvic floor repair." 2010 ICS IUGA Executive Agenda
ETH.MESH.00800521 to ETH.MESH.00800522 Email string, top one from Kenneth Pagel to Melissa Doyle re: presentation access.

Production Materials

ETH.MESH.00806974 to ETH.MESH.00806975 Email from Lissette Caro-Rosado to Jaime Sepulveda, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattyson, et al.
ETH.MESH.00807570 to ETH.MESH.00807570 Revised Chart listing Proposed Lab Schedule
ETH.MESH.00807772 to ETH.MESH.00807774 Email String, top one from Bart Pattyson to Hugo Ye re: ICS-IUGA - Cadaver Lab & Ask the Expert Update; cc: Ping Li, et al.
ETH.MESH.00807972 to ETH.MESH.00807973 Email string, top one from Bart Pattyson to Tommaso Santini, et al. re: US Surgeon; cc: Tom Affeld.
ETH.MESH.00808121 to ETH.MESH.00808122 Email from bart Pattyson to Jaime Sepulveda et al. re: Prosima (&Elevate) Advisory Board - Jan 8th - Baltimore; cc: Piet Hinoul.
ETH.MESH.00817181 to ETH.MESH.00817181 Email from Scott Jones to Kevin Frost and Tom Affeld re: Summit Agenda/Moderator; cc: Matt Henderson, et al.
ETH.MESH.00820634 to ETH.MESH.00820634 Invitation to participate in Gynecare Prosima Virtual Round Table
ETH.MESH.00832749 to ETH.MESH.00832754 Risk Management Report: Prosima Pelvic Floor Repair Kit
ETH.MESH.00833948 to ETH.MESH.00833949 Email from David Robinson to Jessica Shen re: Prosima Study.
ETH.MESH.00834910 to ETH.MESH.00834911 Email string , top one from David Robinson to Price St. Hilaire, et al. re: Prosima Strategic Council; cc: Kevin Mahar.
ETH.MESH.00840886 to ETH.MESH.00840887 Calendar appointment re: Updated: TVT Secur Preceptor Roundtable Forum; created by Dharini Amin.
ETH.MESH.00843043 Email from David Robinson to Jacqutin Bernard, Judith Gault and Jonathan Meek re: cancellation of scheduled Prosima training.
ETH.MESH.00849014-ETH.MESH.00849017
ETH.MESH.00850335 to ETH.MESH.00850336 Email string, top one from David Robinson to Stephanie Kute, Patrice Napoda re: Prosima FDA Review and IFU; cc: Price St. Hilaire, Dan Smith.
ETH.MESH.00851319 to ETH.MESH.00851321 E-mail string, top one from Piet Hinoul to Clifford Volpe and David Robinson re dimensions of the PROSIMA implant
ETH.MESH.00851319-ETH.MESH.00851321
ETH.MESH.00895089 to ETH.MESH.00895091 Email string, top one from Kevin Frost to Vincenza Zaddem re: Prosima in R&D Study.
ETH.MESH.00921692 to ETH.MESH.00921694 Email string, top one from Tom Affeld to Scott Jones, et al. re: NEO #2, 3, 4 Lab Nominations; cc: Vincenza Zaddem.
ETH.MESH.00925065 to ETH.MESH.00925067 Email string, top one from Joshua Samon to Vincenza Zaddem re: Mint Value Proposition; cc: Duan Broughton.
ETH.MESH.01136239 to ETH.MESH.01136240 Email string, top one from Lissette Caro-Rosado to Ad Board Members re: EWH&U Pelvic Floor Repair Ad Board 1-8-11; cc: Tom Affeld, et al.
ETH.MESH.01198058 to ETH.MESH.01198058 (Draft) Zyczynski, H., et al. "One year clinical outcomes after prolapse surgery with non-anchored mesh and vaginal support device."
ETH.MESH.01200286 to ETH.MESH.01200286 Powerpoint: Gynecare Prosima : Overview.
ETH.MESH.01201973 to ETH.MESH.01201973 Propsed Lab Schedule (2nd Revision)
ETH.MESH.01237077 to ETH.MESH.1237079 Email from Piet Hinoul to David Robinson, et al. re: Prosima Take Away Messages; cc: Peter Meier.
ETH.MESH.01244824 to ETH.MESH.01244826 Email string, top one from Aaron Kirkemo to Cyrus Guidry re: response letter to editor, Lewis Wall.
ETH.MESH.01411037 to ETH.MESH.01411039 Summary re: Project Mint

Production Materials

ETH.MESH.02233439 to ETH.MESH.02233451 A New Operation for Vaginal Prolapse Repair Using Mesh and a Vaginal support Device: 1 Year Anatomic and Functional Results of an International, Multicenter Study.
ETH.MESH.02233439 US Training 1-year clinical data
ETH.MESH.02233452 to ETH.MESH.02233467 Prosima - Background and Development History
ETH.MESH.02233452 US Training - Background & history
ETH.MESH.02233539 New Product Request Form 2
ETH.MESH.02233539 to ETH.MESH.02233539 Prosima - New Product Request Form
ETH.MESH.02233540 2009 Sales training
ETH.MESH.02233540 to ETH.MESH.02233625 Prosima - 2009 Sales Training Program
ETH.MESH.02233605 B&W Webinar invite
ETH.MESH.02233605 to ETH.MESH.02233605 (B&W) Webinar Invite "The treatment of Symptomatic Moderate Pelvic Organ Prolapse."
ETH.MESH.02233640 B&W 2-year clinical data
ETH.MESH.02233640 to ETH.MESH.02233640 (B&W) Prosima - Module 4: 2-Year Clinical Data
ETH.MESH.02233651 to ETH.MESH.02233673 One year Clinical Outcomes Following Prolapse Surgery with Non-Anchored Mesh and a Vaginal Support Device. Results from the International Multicenter Gynecare Prosima™ Study.
ETH.MESH.02233674 KF Marketing 1
ETH.MESH.02233674 to ETH.MESH.02233692 (Marketing) "What is Gynecare Prosima Pelvic Floor Repair System?"
ETH.MESH.02233699 Dr. Carey white paper
ETH.MESH.02233699 to ETH.MESH.02233710 Prosima - An Interview with Dr. Marcus P. Carey.
ETH.MESH.02233713 Objective success learning guide
ETH.MESH.02233713 to ETH.MESH.02233714 Objective Success Rate Learning Guide
ETH.MESH.02233726 Ethicon360 12.09
ETH.MESH.02233726 to ETH.MESH.02233727 Prosima Product Page on Ethicon-360
ETH.MESH.02233728 to ETH.MESH.02233728 (native) Gynecare Prosima™ Key Procedural Steps
ETH.MESH.02233834 B&W 2009 Sales Aid Guide
ETH.MESH.02233834 to ETH.MESH.02233834 (B&W) 2009 Sales Aid Guide
ETH.MESH.02233840 MRI Flashcard
ETH.MESH.02233840 to ETH.MESH.02233841 MRI Flashcard "Prosimia - The first fixationless mesh system that maintains anatomical position."
ETH.MESH.02233842 to ETH.MESH.02233842 Virtual Round Table Registration Form
ETH.MESH.02233842 VRT rsvp 9.2010
ETH.MESH.02233843 to ETH.MESH.02233849 Clinical Study Findings Discussion for Gynecare Prosima™ by Piet Hinoul (Audio Transcript).
ETH.MESH.02233851 to ETH.MESH.02233851 Document entitled "PROS-438-10-9/12 Prosima Short Procedural Video."
ETH.MESH.02233857 AJOG Press Release
ETH.MESH.02233857 to ETH.MESH.02233859 AJOG Press Release (Draft)
ETH.MESH.02233862 AALG in booth presentation
ETH.MESH.02233862 to ETH.MESH.02233880 AALG in booth presentation. "Proof in the Treatment of Pelvic Organ Prolapse" Douglas Van Drie, M.D.
ETH.MESH.02233881 to ETH.MESH.02233888 Zyczynski, H.M. "One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device." Am J Obstet Gynecol (2010) 203.

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ETH.MESH.02233961 to ETH.MESH.02233961 Virtual Round Table Follow-up Letter.
ETH.MESH.02233961 VRT follow-up
ETH.MESH.02233962 to ETH.MESH.02233962 Virtual Round Table Follow-up Letter.
ETH.MESH.02233962 VRT2 follow-up
ETH.MESH.02233963 to ETH.MESH.02233963 Virtual Round Table Invitation
ETH.MESH.02233963 VRT invite 9.2010
ETH.MESH.02233964 B&W Prosima DVD
ETH.MESH.02233964 to ETH.MESH.02233964 (B&W) Prosima DVD
ETH.MESH.02234001 KF Marketing 1a
ETH.MESH.02234001 to ETH.MESH.02234002 (Marketing) The Gynecare Prosima™ Pelvic Floor Repair System Story
ETH.MESH.02234005 Sales Training 20
ETH.MESH.02234005 to ETH.MESH.02234171 Prosima Sales Training Program
ETH.MESH.02234173 to ETH.MESH.02234177 Prosima Messgaging practice Coaching Check List
ETH.MESH.02234173 Training checklist
ETH.MESH.02237107 Pt Ethicon epiphany
ETH.MESH.02237107 to ETH.MESH.02237115 Introducing Gynecare Prosima for Ethicon Epiphany 247.
ETH.MESH.02248778 - Mechanical vs Machine Cut (Laser.Ultrasonic) Mesh Particle loss less than 2 percent for both
Eth.Mesh.02293981 Email from Adrian Roji dated 7/19/11 re Approved FDA Notification Response
ETH.MESH.02318553 to ETH.MESH.02318554 Gynecare Prosima™ Combined Pelvic Floor Repair System Clinical Strategy.
ETH.MESH.02322037 to ETH.MESH.02322039 Email string, top one from Piet Hinoul to Aaron Kirkemo, et al. re: Neo clinical trial.
ETH.MESH.02322037-039
ETH.MESH.02341398 to ETH.MESH.02341453 Prosima IFU
ETH.MESH.02597949 to ETH.MESH.02597950 Hinoul, P., et al. "A "mesh" made in heaven: synergy between the urogynaecological device industry and evidence based medicine."
ETH.MESH.02599918 to ETH.MESH.02599920 Email string, top one from Piet Hinoul to Kevin Frost re: 1-year Prosima Data Conference Call.
ETH.MESH.02967410 to ETH.MESH.02967412 Study: Prosima (300-06-005); Plots/charts for 12-month vs. baseline safety analysis set.
ETH.MESH.03048942 to ETH.MESH.03048942 Document entitled "New" Mint January 05, 2006.
ETH.MESH.03049774 to ETH.MESH.03049775 Gynecare Prosima* Combined Pelvic Floor Repair System: Clinical Strategy.
ETH.MESH.03056578 to ETH.MESH.03056580 Email string from Colin Urquhart to David Robinson and Judith Gauld re: Prosima* investigator bulletin.
ETH.MESH.03109341 to ETH.MESH.03109341 Email string, top one from Judi Gauld to Halina Zyczynski re: Prosima well received at AUA.
ETH.MESH.03160821 to ETH.MESH.03160821 Email from Judith Gauld to Allison London Brown re: US Prosima Sites; cc: David Robinson, et al.
ETH.MESH.03160822 to ETH.MESH.03160823 Email string, top one from Judith Gauld to Stephanie Kute re: MINT Design Validation Dates; cc: Dan Smith, et al.
ETH.MESH.03160827 to ETH.MESH.03160828 Email string, top one from Colin Urquhart to Stephanie Kute re: Doctors contacted for DVal as of today; cc: Judith Gauld, et al.
ETH.MESH.03162936 to ETH.MESH.03162938 Email string from Judith Gauld to David Robinson and Jonathan Meek re: Marcus Carey US visit.

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ETH.MESH.03393725 to ETH.MESH.03339731 Sikirica, V, et al. "Sexual Function 12 Months Following Vaginal Prolapse Repair Augmented by Mesh and a Vaginal Support Device" ICS/IUGA (2010) Abstract
ETH.MESH.03396246 to ETH.MESH.03396246 VSD Patient Information (Slim Jim) - "Stop Coping Start Living."
ETH.MESH.03427757 to ETH.MESH.03427759 EWHU eClinical Compendium - Article Summary. Barber, M.D., et al. "Transobturator Tape Compared with Tension-free Vaginal Tape for the Treatment of Stress Urinary Incontinence: A Randomized Controlled Trial.
ETH.MESH.03439842 to ETH.MESH.03439846 Prosima Sales Aid Training Deck - "What could a truly tension-free repair mean for you and your patients?"
ETH.MESH.03440816 to ETH.MESH.03440836 Prosima Revised Webinar Deck - Overview
ETH.MESH.03471308 to ETH.MESH.03471308 Chart entitled "Pedm Monthly Status."
ETH.MESH.03612364 to ETH.MESH.03612364 Gynecare Prosima Pelvic Floor Repair Preceptorship, Course Overview.
ETH.MESH.03626267 to ETH.MESH.03626269 Email string, top one from Jennifer Paradise to Susie Chilcoat re: Prosima Professional Education Slide Deck Conference Call.
ETH.MESH.03643392 to ETH.MESH.03643395 Email string, top one from Jennifer Paradise to Adrian Roji, et al. re: Approved for distribution: FDA Notification FAQs and Customer Letter.
ETH.MESH.03959337 - Prolift+M vs. Prosima - 2 year results
Eth.Mesh.03962244 Dear Surgeon letter 7/18/11
ETH.MESH.03984409 to ETH.MESH.03984410 Email string, top one from Scott Finley to Greg Prine re: Pelvic Floor Repair Customer Meeting.
ETH.MESH.03989722 to ETH.MESH.03989723 Email string, top one from Jim Gatewood to Rebecca Ryder re: Prosima 2 Year data Dinner.
ETH.MESH.03989781 to ETH.MESH.03989782 Email from Jim Gatewood to Marilyn Valdes re: Norfolk, VA, Dec 2, 2010 Prosima Awareness Dinner Information.
ETH.MESH.03991591 to ETH.MESH.03991592 Memo re: Gynecare Studies; created by Randall Gore.
ETH.MESH.04042511 to ETH.MESH.04042512 Slack, M., et al. Presentation Title: "Clinical Experience of a Novel Vaginal Support Device and Balloon used to Simplify Mesh Augmented Vaginal surgery for Prolapse."
ETH.MESH.04077172 to ETH.MESH.04077172 Powerpoint: Gynecare LatAm Moments at IUGA Congress 2010
ETH.MESH.04206959
ETH.MESH.04381806 to ETH.MESH.04381819 Literature Review on Biocompatibility of Prolene Sutures and Impants
ETH.MESH.04427456 to ETH.MESH.14427457 FDA Letter re: K063562 Gynecare Prosima Pelvic Floor Repair Systems
Eth.Mesh.04543335 Pelvic Organ Prolapse Surgical Mesh Discussion call in information 9/12/11
Eth.Mesh.04543336 Pelvic Organ Prolapse Surgical Mesh Discussion call in information 9/12/11
ETH.MESH.04543336- POP Surgical Mesh Discussion 09.12
ETH.MESH.04550996 to ETH.MESH.04550997 Email string, top one from Piet Hinoul to Marcus Carey and Richard Gooding re: Prosima VSD.
ETH.MESH.04550996 to ETH.MESH.04550997 Email string, top one from Piet Hinoul to Marcus Carey re: Prosima VSD.
ETH.MESH.04551757 to ETH.MESH.04551795 E-mail with attachment from Piet Hinoul to Jeffrey Hammond, Dr. James Hart, et al. regarding Benefit risk profile TVM
Eth.Mesh.04551946 Ethicon Gynecare WW Commercialization Decision – US Surgeon Letter 6/1/12

Production Materials

Eth.Mesh.04554662 Ethicon Gynecare WW Commercialization Decision – US Frequently Asked Questions 6/1/12
Eth.Mesh.04567174 Ethicon Gynecare US Commercialization Decision – US Discussion Guide for Use with Customers 5/15/12
Eth.Mesh.04567674 Ethicon Gynecare US Commercialization Decision – Core Messages 5/15/12
Eth.Mesh.04567677-04567679 Frequently asked questions 5/15/12
Eth.Mesh.04567680-04567681 Message from Laura Angelini to Internal WW Associates 5/15/12
Eth.Mesh.04567686-04567679 US Sales Call Script for Matt Henderson 5/15/12
Eth.Mesh.04567695 Ethicon Gynecare WW Commercialization Decision – Core Messages 6/1/12
Eth.Mesh.04567698 Ethicon Gynecare WW Commercialization Decision – Standby Statement 6/1/12
Eth.Mesh.04567707 Ethicon Gynecare WW Commercialization Decision – Chuck Austin Message to WW General Surgery Employees 6/1/12
Eth.Mesh.04567726 Ethicon Gynecare WW Commercialization Decision – Tim Schmid message to US General Surgery Employees 6/1/12
ETH.MESH.04568519 to ETH.MESH.04568519 Email from Matt Henderson to Tim Schmid re: 522 Communication Recap.
ETH.MESH.05092843 to ETH.MESH.05092843 Chart listing lab schedule for August 11th.
ETH.MESH.05106233 to ETH.MESH.05106234 Email string, top one from Kevin Frost to danhalt@gmail.com, et al. re: Reminder: Prosima Professional Education Slide Deck Conference Call Tonight 7pm EST.
ETH.MESH.05164225 to ETH.MESH.05164226 EWHU eClinical Compendium - Article Summary. Reisenauer, C., et al. "Anatomic study of prolapse surgery with nonanchored mesg and a vaginal support device."
ETH.MESH.05165675 to ETH.MESH.05165677 EWHU eClinical Compendium - Article Summary. Barber, M.D., et al. "Defining success after surgery for pelvic organ prolapse." Obstet Gynecol (2009) 114:600-609.
ETH.MESH.05217098 to ETH.MESH.05217100 FDA Clearance Letter, Modified PROLENE
ETH.MESH.05217103 to ETH.MESH.05217144 Letter to FDA re: Notification of Intent
ETH.MESH.05343480 to ETH.MESH.05343482 Email string, top one from Joseph Lanza to Bart Pattyson re: Review EWHU IUGA events.
ETH.MESH.05343757 to ETH.MESH.05343758 Email string, top one from Kevin Frost to Bart Pattyson re: July 31 Heads Up; cc: Lissette Caro-Rosado.
ETH.MESH.05469908 to ETH.MESH.05469912 Email string, top one from Thomas Barbolt to Dr. Joerg Holste, et al. re: Ultrapro; cc: Laura Angelini, et al.
ETH.MESH.05469908-912
ETH.MESH.05571741 to ETH.MESH.05571741 Email string, top one from Jim Gatewood to Robert Zipfel re: Gynecare Prof Ed - Approved: Request for Speaker Event.
ETH.MESH.05573916 to ETH.MESH.05573917 Email string, top one from Kevin Frost to Jennifer Paradise re: Prosima VRT Reminder - Honoraria Payments; cc: Paul Parisi.
ETH.MESH.05741094 to ETH.MESH.05741094 Email from Rhonda Peebles to Samuel Sheelu, et al. re: Additional room for Ask the Expert sessions; cc: Alyson Wess, et al.
ETH.MESH.05741890 to ETH.MESH.05741891 Email string, top one from Christopher Teasdale to Tom Affeld, et al. re: Additional room for Ask the Experts sessions.
ETH.MESH.05835298 to ETH.MESH.05835308 Pelvic Organ Prolapse - Patient Counseling Guide.
ETH.MESH.05837063 to ETH.MESH.05837110 Pelvic Organ Prolapse Value Dossier. Gynecare Prolift, Gynecare Prolift +M, Gynecare Prosima.

Production Materials

ETH.MESH.05840629 to ETH.MESH.05840629 Powerpoint Presentation entitled "Continuum of Education."
ETH.MESH.05922038 to ETH.MESH.05922038 Letter from Patricia Nevar to Jaime Sepulveda, M.D. re: Secrecy Agreement for Prosima.
ETH.MESH.05947160 to ETH.MESH.05947163 Email from Patricia Holland to Andre Fontes re: Partnership Plus Follow up _Gynecare_Reminder; cc: Fernando Nassif, et al.
ETH.MESH.05967586 to ETH.MESH.05967587 Email string, top one from Robert Zipfel to Susie Chilcoat re: Prosima Preceptor-Led Virtual Round Tables (VRTs) faculty payment.
ETH.MESH.06113091 to ETH.MESH.06113092 Email from Debra Mayfield to DL-ETHUSSO EWHU WESTERN REGION re: Prosima VRT Invitation Plan - due Jan 28.
ETH.MESH.06124656 to ETH.MESH.06124657 Email string, top one from Andrew Meek to Bart Pattyson re: Prosima training.
ETH.MESH.06124954 to ETH.MESH.06124955 Email string, top one from Bart Pattyson to Marcos Fujihara re: Prosima training in Miami with Dr. Jaime Sepulveda.
ETH.MESH.06125000 to ETH.MESH.06125001 Email string, top one from Bart Pattyson to Robert Zipfel re: Prosima in LATAM.
ETH.MESH.06125058 to ETH.MESH.06125058 Email from Bart Pattyson to Eugene Brohee re: June 21 - Latin America doctors in town; cc: Selena Lessa.
ETH.MESH.06125098 to ETH.MESH.06125098 Email string, top one from Bart Pattyson to Georgia Long re: updated agenda - May 8th.
ETH.MESH.06125277 to ETH.MESH.06125277 Email string, top one from Marcos Fujihara to Bart Pattyson, et al. re: Prosima presentation in Miami.
ETH.MESH.06125309 to ETH.MESH.06125309 Email string, top one from Robert Zipfel to Bart Pattyson re: Prosima in LATAM.
ETH.MESH.06125502 to ETH.MESH.06125502 Email string, top one from Georgia Long to Bart Pattyson re: may 8th.
ETH.MESH.06151466 to ETH.MESH.06151467 Email string, top one from David Robinson to Judith Gauld re: Jaime Sepulveda.
ETH.MESH.06238611 to ETH.MESH.06238611 Email from Mark Kenyon to Aaron Kirkemo re: NEO Surgical Guide - Role & Responsibilities; cc: Vincenza Zaddem.
ETH.MESH.06255523 to ETH.MESH.06255534 Gynecare Prosima ™ Pelvic Floor Repair System. "An Expert Interview with Dr. Marcus P. Carey, MBBS, FRANZCOG, CU, the Inventor of the Gynecare Prosima System."
ETH.MESH.06388151 to ETH.MESH.06388151 Powerpoint: Prolift Pelvic Floor Repair - MDV Reported Complaints
ETH.MESH.06480608 to ETH.MESH.06480609 Email string, top one from Judith Gauld to Stephanie Kute re: MINT Design Validation Dates; cc: Dan Smith, et al.
ETH.MESH.06482821 to ETH.MESH.06482822 Email from Judith Gauld to Tony Smith re: Prosima Investigator Meeting; cc: David Robinson.
ETH.MESH.06585815 to ETH.MESH.06585815 Powerpoint: Agenda
ETH.MESH.06591558 to ETH.MESH.06591559 Email string, top one from Tom Affeld to Shwetal Narvekar re: Pre-launch Awareness for Prosima with Dr. Marcus Carey; cc: Bart Pattyson, et al.
ETH.MESH.06769156 to ETH.MESH.06769156 Powerpoint: A New Operation for Vaginal Prolapse Repair Using Mesh and a Vaginal Support Device: 1 Year Anatomic and Functional Results of an International, Multicenter Study. Mark Slack, Cambridge, UK for the Prosima Study Group.
ETH.MESH.07105727 to ETH.MESH.07105727 Email string, top one from Laura Vellucci to Colin Urquhart re: Prosima publication.

Production Materials

ETH.MESH.07189091 to ETH.MESH.07189091 Powerpoint: From presentation to publication: ensuring quality in the reporting of urogynaecology research. IUGA "This house believes that industry sponsorship has a corrosive influence on standards of scientific reporting." Conflict of interests: Piet Hinoul, M.D.
ETH.MESH.07190144 to ETH.MESH.07090145 Email string, top one from Judi Gauld to Piet Hinoul, Colin Urquhart re: +M Abstract.
ETH.MESH.07219196 to ETH.MESH.07219209 Clinical Expert Report - Prosima [™] signed by David Robinson.
ETH.MESH.07229215 to ETH.MESH.07229245 Clinical Expert Report - Prosima [™] signed by Piet Hinoul.
ETH.MESH.07296496 to ETH.MESH.07296496 Chart listing Week Schedule and Lab Flow.
ETH.MESH.07308636 to ETH.MESH.07308637 Email from Tom Affeld to Clifford Volpe, et al. re: Surgeon's view on Prosima; cc: Lissette Caro-Rosado, et al.
ETH.MESH.07324554-555
ETH.MESH.07374762 to ETH.MESH.07374763 Email from Lissette Caro-Rosado to Jaime Sepulveda, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattyson, et al.
ETH.MESH.07379573 to ETH.MESH.07379574 Email string, top one from Kevin Frost to Ahmet Bedestani, et al. re: Purpose; cc: Matt Henderson, et al.
ETH.MESH.07384790 to ETH.MESH.07384791 Email string, top one from Robert Zipfel to Lissette Caro-Rosado re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones, and Schlafstein on Monday Jan 4, 2010.
Eth.Mesh.07462313 Email from Adrian Roji dated 8/19/11 re update message to the field re FDA notification response
ETH.MESH.07587090 to ETH.MESH.07587091 Email string, top one from Judith Gauld to Patricia Nevar re: Dr. Sepulveda; cc: Colin Urquhart.
ETH.MESH.07628243 to ETH.MESH.07628243 EWH&U Gynecare Prosima [™] Pelvic Floor Repair System Faculty Checklist.
ETH.MESH.07630654 to ETH.MESH.07630654 Email string, top one from Greg Prine to Stevan Barendse, Robert Zipfel re: Prosima targets.
ETH.MESH.07631488 to ETH.MESH.07631488 Email string, top one from Selena Lessa to Robert Zipfel re: Prosima course with Sepulveda.
ETH.MESH.07631752 to ETH.MESH.07631753 Email string, top one from Eric Globerman to Nicole Huffman re: Prosima course; cc: Robert Zipfel.
ETH.MESH.07631967 to ETH.MESH.07631968 Email string, top one from Stacy Hoffman to Robert Zipfel, Kimberly Heath re: Prosima Lab.
ETH.MESH.07632042 to ETH.MESH.07632042 Event request form for Sepulveda Preceptorship.
ETH.MESH.07632042 to ETH.MESH.07632043 Email from Kevin Frost to danhalt@gmail.com, et al. re: Save the Date: Prosima Faculty Conference Call 7/20 at 7pm EST; cc: Jennifer Paradise.
ETH.MESH.07636090 to ETH.MESH.07636090 Prosima Cadaver Lab Invitation
ETH.MESH.07653362 to ETH.MESH.07653363 Email string, top one from Tommaso Santini to Kevin Frost, et al. re: US Surgeon; cc: Tom Affeld.
ETH.MESH.07931680 to ETH.MESH.07931681 Email string, top one from Bart Pattyson to Jeff Hsieh re: Prosima Professional Education Slide Deck Conference Call.
ETH.MESH.07951163 to ETH.MESH.07951163 Document re: Prosima's apical/anatomical success rates and functional outcomes.
ETH.MESH.07953429 to ETH.MESH.07953433 EWH&U 2011 Field Visit Letter
ETH.MESH.07977911 to ETH.MESH.07977911

Production Materials

ETH.MESH.08021804 to ETH.MESH.08021807 Email string, top one from Libby Lewis to Kenneth Pagel, et al. re: Journal Club - trocar-less vaginal mesh kits.
ETH.MESH.08023741 to ETH.MESH.08023744 Email string, top one from Scott Miller to Jonathan Fernandez re: Prosima Take Away Messages.
ETH.MESH.08033153 to ETH.MESH.08033153 Document entitled "Prevalence and risk factors for mesh erosion after laparoscopic-assisted sacrocolpopexy." Author(s) Jasmine Tan-Kim, Shawn A, Menefree, Karl M, Lubner, Charles W. Nager, Emily S. Lukacz.
ETH.MESH.08048738 to ETH.MESH.08048740 Email from David Jackson to Selena Lessa re: Prosima course with Sepulveda.
ETH.MESH.08066452 to ETH.MESH.08066452
ETH.MESH.08135444 to ETH.MESH.08135444 Gynecare Prosima - Pelvic Floor Repair System Proctorship
ETH.MESH.08139049 to ETH.MESH.08139118 Pelvic Organ Prolapse - The Role of Prosima. Author: Mark Slack.
ETH.MESH.08161765 to ETH.MESH.08161765 Email from Suzy Taylor to Jared Aldridge, et al. re: Follow up to FDA Mesh Advisory.
ETH.MESH.08169582 to ETH.MESH.08169620 Surgical Practice of POP survey on Survey Monkey.
ETH.MESH.08290691 to ETH.MESH.08290691
ETH.MESH.08309057 to ETH.MESH.08309092 Document entitled "Benefit-Risk Profile of Ethicon, Inc.'s Pelvic Organ Prolapse Mesh Repair Products."
ETH.MESH.08375158 to ETH.MESH.08375159 Email string, top one from Larry Gillihan to Kenneth Pagel, Jason Hernandez re: New Product Tabs - TVT Abbrevio, Prosima, TVT Exact.
ETH.MESH.08384247 to ETH.MESH.08384247
ETH.MESH.08384270 to ETH.MESH.08384270 Email string, top one from Lisa Pitts to Paul Saliba re: Prosima pearls from Dr. Garriss.
Eth.Mesh.08421628 Ethicon Gynecare WW Commercialization Decision - US Customer Discussion Guide 6/1/12
ETH.MESH.08492824
ETH.MESH.08492824 to ETH.MESH.08492824 Strategic Business Team Meeting - Meeting Notes
Eth.Mesh.08640676 Jones email 4/04/08 re Prosima update for RBDs
ETH.MESH.08945734 to ETH.MESH.08945735 ICS-IUGA 2010 Abstract Form. "Ultrasound assessment 6 months following vaginal prolapse surgery using polypropylene implants and a vaginal support device."
ETH.MESH.08945742 to ETH.MESH.08945744 Presentation Title: A New Operation for Vaginal Prolapse Repair using Mesh and a Vaginal Support Device: 1 Year Anatomic and Functional Results of an International, Multicentre Study." Presenter: Slack, M., et al.
ETH.MESH.08945836 to ETH.MESH.08945840 Document entitled "Gynecare Prosima Claims List."
ETH.MESH.08948364 to ETH.MESH.08948365 Email string, top one from Kevin Frost to William Rush re: Save the Date: Prosima 2 Year Clinical Data Review; cc: Tom Affeld.
ETH.MESH.08951725 to ETH.MESH.08951726 Email string, top one from Tom Affeld to Kevin Frost re: Prosima 2 year summary for eClinical Compendium.
ETH.MESH.08962682 to ETH.MESH.08962683 Email from Helen Wong to Kevin Frost re: Sepulveda's comment on the VRT; cc: Jenny Krieger, et al.
ETH.MESH.08962684 to ETH.MESH.08962685 Email string, top one from Jenny Krieger to Kevin Frost re: Reminder: Prosima Teleconference today.
ETH.MESH.08971152 to ETH.MESH.08971153 Email string, top one from Kevin Frost to Libby Lewis re: Prosima VRT Invitation plan - due Jan 28.

Production Materials

ETH.MESH.08971269 to ETH.MESH.08971270 Email string, top one from Kevin Frost to Aaron Kirkemo, Piet Hinoul re: Prosima VRT: fill-in.
ETH.MESH.08971271 to ETH.MESH.08971272 Email string, top one from Kevin Frost to Marilyn Valdes re: Dr. Sepulveda availability on 1/31.
ETH.MESH.08971309 to ETH.MESH.08971314 Email string, top one from Kevin Frost to Helen Wong re: Dr. Sepulveda's 1/31 VRT; cc: Jenny Krieger.
ETH.MESH.08988155 to ETH.MESH.08988155 Powerpoint: Gynecare Prosima™ Pelvic Floor Repair System: Background. Halina Zyczynski, M.D.
ETH.MESH.08988298 to ETH.MESH.08988417 EBM - Pelvic Organ Prolapse Clinical References: 2002-2011, including Prolift, Prolift+M, Prosima, Gynemesh. Searcher: Kerry Kushinka.
ETH.MESH.09050450 to ETH.MESH.09050450 Memorandum from David Robinson re: the compatibility if estrogen creams with Prosima balloon and vaginal support device. (Not signed).
ETH.MESH.09128451 to ETH.MESH.09128451 Chart entitled "Faculty Training."
Eth.Mesh.09128545 Pelvic Organ Prolapse Surgical Mesh Discussion call in information 8/25/11
ETH.MESH.09128545- POP Surgical Mesh Discussion 08.25
ETH.MESH.09138054 to ETH.MESH.09138055 Information re: Jaime Sepulveda, M.D. and Arthur Mourtzinis, M.D.
ETH.MESH.09142383 to ETH.MESH.09142384 Email from Kevin Frost to danhalt@gmail.com, et al. re: Save the Date: Prosima Faculty Conference Call 7/20 at 7pm EST; cc: Jennifer Paradise.
ETH.MESH.09142511 to ETH.MESH.09142511 (Draft) EWHU Memo from Bart Pattyson (US Marketing and Professional Education) to US Faculty Members re: Gynecare Prosima - Pelvic Floor Repair System, Updated Professional Education Deck.
ETH.MESH.09144349 to ETH.MESH.09144349 Powerpoint: Ethicon Women's Health and Urology: Clinical Expertise Road Map.
ETH.MESH.09191424 to ETH.MESH.09191426 Email string, top one from Hemangini Patel to Carolina Guzman re: Final Draft report for Prosima - Urgent; cc: Irene Leslie, Rosangela Ribeiro.
ETH.MESH.09207059 to ETH.MESH.09207059 Chart entitled "Grier."
ETH.MESH.09218452 to ETH.MESH.09218453 Email string, top one from Rhonda Peebles to Andrew Meek re: Remaining 2010 labs; cc: Kevin Frost, et al.
ETH.MESH.09283030 to ETH.MESH.09283030 Spreadsheet re: Open Incontinence & AP.
ETH.MESH.09283031 to ETH.MESH.09283031 Spreadsheet re: Open Incontinence & AP.
ETH.MESH.09283032 to ETH.MESH.09283032 Spreadsheet re: Pelvic Floor Repair
ETH.MESH.09283033 to ETH.MESH.09283033 Spreadsheet re: Budget Summary
ETH.MESH.09283034 to ETH.MESH.09283034 Spreadsheet re: Integrated Marketing
ETH.MESH.09283035 to ETH.MESH.09283035 Spreadsheet re: Summary
ETH.MESH.09283036 to ETH.MESH.09283036 Spreadsheet re: Pelvic Floor Repair
ETH.MESH.09283037 to ETH.MESH.09283037 Spreadsheet re: Budget Summary
ETH.MESH.09283038 to ETH.MESH.09283038 Spreadsheet re: Integrated Marketing
ETH.MESH.09290755 to ETH.MESH.09290755 Spreadsheet re: Q1 2012 Open PO Summary
ETH.MESH.09290760 to ETH.MESH.09290760 Spreadsheet re: Open Incontinence & AP.
ETH.MESH.09290767 to ETH.MESH.09290767 Spreadsheet re: Uterine Health
ETH.MESH.09290769 to ETH.MESH.09290769 Spreadsheet re: Ethicon Gynecare May 2012 Open PO Summary
ETH.MESH.09290772 to ETH.MESH.09290772 Spreadsheet re: Budget Summary
ETH.MESH.09300480 to ETH.MESH.09300480 Spreadsheet re: Prosima All Day
ETH.MESH.09625725 to ETH.MESH.09625729 Government Submissions Log Sheet

Production Materials

ETH.MESH.09625731 to ETH.MESH.09625737 FDA Letter. re: approved drug application for polypropylene suture.
ETH.MESH.09625816 to ETH.MESH.09625816 FDA letter re: receipt of drug application for polypropylene suture.
ETH.MESH.09625817 to ETH.MESH.09625817 Letter to FDA re: new drug application for Polypropylene Suture.
ETH.MESH.09629447 to ETH.MESH.09629448 FDA Labeling Approval for Prolene
ETH.MESH.09630649 to ETH.MESH.09630649 FDA Letter re: package insert for Prolene.
ETH.MESH.09634081 to ETH.MESH.09634081 Sections 6 re: adverse effects.
ETH.MESH.09634299 to ETH.MESH.09634303 FDA Letter re: approval of PMA supplement.
ETH.MESH.09634318 to ETH.MESH.09634318 Prolene Package Insert.
ETH.MESH.09634662 to ETH.MESH.09634663 FDA Letter re: reclassification of Nonabsorbable Polypropylene Surgical Suture.
ETH.MESH.09634664 to ETH.MESH.09634688 FDA Letter re: reclassification of Nonabsorbable Polypropylene Surgical Suture.
ETH.MESH.10048035 to ETH.MESH.10048036 Email from Mark Pare to Walter Boldish, et al. re: Clinical #2 - Prosima; cc: Elizabeth David, et al.
ETH.MESH.10179518 to ETH.MESH.10179636 Clinical Evaluation Report - Gynecare Gynemesh™ PS Nonabsorbable Prolene™ Soft Mesh signed by Piet Hinoul.
ETH.MESH.10224077 to ETH.MESH.10224077 Email string, top one from Molly Dugan to Greg Prine re: Prosima Lab Feedback; cc: Joseph Drabik.
ETH.MESH.10232708 to ETH.MESH.10232708 Email from Stevan Barendse to Greg Prine re: Prosima targets.
ETH.MESH.10376963
ETH.MESH.10384309-310
ETH.MESH.10399553 to ETH.MESH.10399554 Email from Judi Gauld to Marcus Carey, et al. re: Prosima presentation at AUA; cc: David Robinson, et al.
ETH.MESH.10608341 to ETH.MESH.10608357 Post Market Surveillance Report. Pelvic Floor Repair Systems. Gynecare Prolift, Gynecare Prolift+M and Gynecare Prosima.
Eth.Mesh.10817931 Pelvic Mesh Post-Market Surveillance Orders April 2012
ETH.MESH.10960414 to ETH.MESH.10960414 Email from Christopher O'Hara to Francois Barbe, et al. re: VRT for Prosima.
ETH.MESH.11048537 to ETH.MESH.11048538 Prosima E-blast No. 1 "The Proof of Success."
ETH.MESH.11448841 Conference Participant Report 8/25/11
ETH.MESH.11518663 to ETH.MESH.11518665 Email string, top one from Melissa Doyle to Arthur Mourtzinis re: Agenda for tomorrow's lab.
ETH.MESH.11522550 to ETH.MESH.11522551 Email string, top one from Melissa Doyle to Seth Moskos re: VSD "take home" instructions.
ETH.MESH.11523079 to ETH.MESH.11523079 Email from Melissa Doyle to Walter Boldish, et al. re: Lahey Labs September 18, 2010; cc: Carole Carter-Cleaver.
ETH.MESH.11524125 to ETH.MESH.11524128 Email string, top one from Melissa Doyle to Andrew Meek re: Upcoming Labs - planning.
ETH.MESH.11536046 to ETH.MESH.11536046 Email string, top one from Jonathan Fernandez to Rhonda Peebles re: Remaining 2010 labs; cc: Robert Zipfel, et al.
ETH.MESH.11905619 to ETH.MESH.11905619 Spreadsheet: Prosima Virtual Roundtable Calls &Targets

Production Materials

ETH.MESH.12897617 to ETH.MESH.12897678 Clinical Evaluation Report - Prosima™ signed by Piet Hinoul.
ETH.MESH.13314554 to ETH.MESH.13314554 Email from Laura Hance to Dr. Lowden re: Prosima answer to JP drain and hydrodissection.
Eth.Mesh.13532200 Ethicon Gynecare WW Commercialization Decision - US Sales Call Script 6/1/12
ETH.MESH.13592561 to ETH.MESH.13592561 Prosima Trainee Invitation "Advanced Pelvic Floor Course with Gynecare Prosima"
ETH.MESH.13618003 to ETH.MESH.13618004 EWHU eClinical Compendium - Article Summary. Reisenauer, C., et al. "Anatomic study of prolapse surgery with nonanchored mesh and a vaginal support device."
ETH.MESH.13618029 to ETH.MESH.13618031 EWHU eClinical Compendium - Article Summary. Zyczynski, H.M., et al. "One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device."
ETH.MESH.13622000 to ETH.MESH.13622070 Prosima Trainee Deck Distribution
ETH.MESH.1363575.NATIVE
ETH.MESH.13645631 to ETH.MESH.13645631 DVD - Thoughts on Prolift+M and Prosima from Drs. Michel Cosson and Marcus Carey.
ETH.MESH.13698543 to ETH.MESH.13698543 Prosima Marketing Material Roll-Out Letter.
ETH.MESH.13699674 to ETH.MESH.13699754 Clinical Study Report: A Prospective, Multi-centre Study to Evaluate the Clinical Performance of the Gynecare Prosima™ Pelvic Floor Repair System as a Procedure for Pelvic Organ Prolapse.
ETH.MESH.13756212 to ETH.MESH.13756218 Clinical study Finding Discussion for Gynecare Prosima™ Pelvic Floor Repair System by Piet Hinoul (Audio Transcript).
ETH.MESH.13756219 to ETH.MESH.13756219 Gynecare Prosima™ Pelvic Floor Repair System MRI Address
ETH.MESH.13756384 to ETH.MESH.13756384 Prosima Virtual Round Table Trainee Confirmation
ETH.MESH.13756409 to ETH.MESH.13756409 Prosima Virtual Round Table Preceptor Follow-up and Invitation.
ETH.MESH.13756416 to ETH.MESH.13756417 Prosima Virtual Round Table Preceptor Confirmation.
ETH.MESH.13869166 to ETH.MESH.13869166 Powerpoint: Mint Project - Pelvic Floor Repair.
ETH.MESH.14427453 to ETH.MESH.14427455 FDA Clearance Letter re: K063562 Gynecare Prosima™
ETH.MESH.14427459 to ETH.MESH.14427543 Letter to FDA re: 510(k) K063562 S1, response to deficiencies email.
ETH.MESH.14427562 to ETH.MESH.14427563 Memo to Prosima Regulatory File. Minutes from Teleconference with FDA for Prosima 510(k).
ETH.MESH.14427564 to ETH.MESH.14427565 FDA Letter re: K063562 Gynecare Prosima Premarket Notification 510(k)
ETH.MESH.14427567 to ETH.MESH.14427569 Email from Nada Hanafi to Patrice Napoda re: K063562 Gynecare Prosima.
ETH.MESH.14427578 to ETH.MESH.14427761 Traditionsl 510(k) Premarket Notification Gynecare Prosima™ Pelvic Floor Repair System.
ETH.MESH.15958178 to ETH.MESH.15958182 Email string, top one from Brian Luscombe to Tom Affeld re: Approved for distribution: FDA Notification FAQs and Customer Letter.
Eth.Mesh.16259973 Email from Lisa Jannone dated 1/5/12 re message from Lesley Fronio re update on recent media reports
ETH.MESH.16350627 to ETH.MESH.16350628 Email string, top one from Piet Hinoul to Paan Hermansson re: key message for upcoming Prosima launch.

Production Materials

ETH.MESH.16352932 to ETH.MESH.16352934 Email from Paan Hermansson to Sonja Willems, et al. re: Great EWH&U success at ICS/IUGA congress in Toronto; cc: Bernhard Fischer, et al.
ETH.MESH.16352932-934
ETH.MESH.17669942 to ETH.MESH.17669942 Email from Robert Zipfel tp Elizabeth David, et al. re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones and Schlafstein on Monday Jan 4, 2010.
ETH.MESH.17748760 to ETH.MESH.17748761 E-mail from Kevin Frost regarding 2011 Incontinence & Pelvic Floor Recap
ETH.MESH.17748760-761- Email 4.25.11 FW: 2011 Incontinence & Pelvic Floor Recap
ETH.MESH.18844812 to ETH.MESH.18844812 Email from Patrick Kaminski to Robert Zipfel re: Dr. Thomas Antonini; cc: Stevan Barendse.
ETH.MESH.19308264 to ETH.MESH.19308265 Email from Walter Boldish to Stefanie Garbarino re: Prosima cadaver labs.
ETH.MESH.19310234 to ETH.MESH.19310238 Email string, top one from Stefanie Garbarino to Dr. Maxwell re: TVT-O
ETH-00797 to ETH-00829 510(k) Notification Gynemesh Prolene™ Soft Nonabsorbable Synthetic Surgical Mesh.
ETH-00807 to ETH-00808 FDA Clearance letter for Gynemesh soft mesh for pelvic floor repair
ETH-00830 to ETH-00861 Labeling/Package Insert
ETH-00862 to ETH-00893 Test Method for the Determination of Mesh Burst Strength for Prolene Soft Mesh.
ETH-00894 to ETH-00927 Medical Literature
ETH-01816 to ETH-01817 FDA Clearance Letter, Prolene Soft Mesh (K001122)
Ethicon Biocompatibility Risk Assessment for Gynecare Prolift Total Pelvic Floor Repair System dated 1.19.05 [ETH.MESH.01310817 – 10829]
Ethicon Final Report, PSE Accession No. 00-0035 An Exploratory 91-day Tissue Reaction Study of Polypropylene-Based Surgical Mesh in Rats (PSE Acc. No. 00-0035)
Ethicon informs FDA of discontinuation [ETH.MESH.04005090]
Ethicon informs FDA of discontinuation [ETH.MESH.04005090-91]
Ethicon Technical Report: Assessment of Competitor Pelvic Floor Repair Meshes, Version 1; Study Number: CPC-2006-0552; JJ-HMREV-00016715
Ethicon Women's Health & Urology — Clinical Compendium — Sales Rep Positioning [ETH.MESH.0011879; ETH.MESH.00093830]
Ethicon's Cover Letter Response to TVT Secur 522 Order [ETH.MESH.04474731]
Ethicon's Notification to FDA regarding Decommercialization [ETH.MESH.04005095-96]
Ethicon's Notification to FDA to Decommercialize [ETH.MESH.04005092-93]
Ethicon's TVT Secur Postmarket Surveillance Study Plan: {S120095; Gynecare TVT Secur System [ETH.MESH.04474733]
EWHU Faculty and PF User Conference Calls Outline
Exh. 10 Gynecare Prolift IFU dated 2004 [ETH-00295 – 00300]
Exh. 15 Letter to Bryan Lisa from Mark M. Melkerson with FDA stamped 5.15.08 re: K071512 Gynecare Prolift with attached 510(k) K071512 [ETH-01363 – 01365]
Exh. 59 – Gynecare Prolift Pelvic Floor Repair System Physician Learner Profile (2 pages)
FDA letter to Ethicon re 522 Orders (Kanerviko 2013-08-22 29) [ETH.MESH.04554687]
FDA posting FDA Safety Communication: Update on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse issued 7.13.11 [ETH.MESH.06049894-96]

FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence issued 10.20.08; Information on Surgical Mesh for Pelvic Organ Prolapse and Stress Urinary Incontinence posted by FDA dated 10.23.08 at bottom; Information on Surgical Mesh for Hernia Repairs posted by FDA dated 10.23.08 [ETH.MESH.02105765-02105771]
FDA's Response to proposed study plan-04.02.2012 [ETH.MESH.04567040-44]
FDA's Resposne to Discontinuation and Agreement to Hold 522 Responses [ETH.MESH.04567080]
FDA's Resposne to Discontinuation Notification-07.09.2012 [ETH.MESH.04927339-40]
Final Report, PSE Accession No. 97-0197, Project No. 16672 [ETH.MESH.5315252-65]
Guidance for Industry and FDA Staff. "Class II Special Controls Guidnace Document: Surgical sutures; Guidnace for Industry and FDA."
Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance. "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh."
Gynecare Gynemesh PS a New Mesh for Pelvic Floor Repair Early Clinical Experience [ETH.MESH.03736120-27]
Gynecare Gynemesh PS a New Mesh for Pelvic Floor Repair Early Clinical Experience dated in 2003 (8 pgs)
Gynecare Prolift IFU dated 2009 [ETH-10977 – 10983]
Gynecare Prolift Pelvic Floor Repair System Physician Learner Profile [ETH.MESH.04181761-2]
Gynecare Prolift Pelvic Floor Repair System Total, Anterior and Posterior Pelvic Floor Repair Surgical Technique (30 pgs)
Gynecare Prolift Pelvic Floor Repair System Total, Anterior and Posterior Pelvic Floor Repair Surgical Technique [ETH-07252 – ETH-7281]
Gynecare Prosima - Content for Ethicon360.com
Gynecare Prosima (K063562) Summary of Safety and Effectiveness
Gynecare Prosima Pelvic Floor Repair System: An expert interview with Dr. Marcus P. Carey, MBBS, FRANZCOG, CU, the inventor of the Gynecare Prosima system [ETH.MESH.06255523-34]
Gynecare Prosima updates to ethicon360.com
Gynecare TVT Obturator System Sales Materials [ETH.MESH.161953-54]
Gynecare TVT Tension-free Support for Incontinence: Advanced Users Forum for the Experienced Clinician [ETH.MESH.10220659]
Gynecare TVT Tension-free Support for Incontinence: Professional Education Slides [ETH.MESH.08107354]
Gynemesh PS Approval File from FDA website (K013718)
History of TVT [ETH.MESH.03932912-14]
History of TVT-O [ETH.MESH.3932909-11]
Jan 2007 email re delaying launch [ETH.MESH.18844812]
JJM.Mesh.00043703 Response Statement and FAQS – FDA Notification about use of surgical mesh to treat pelvic organ prolapse and stress urinary incontinence
Kanerviko email re 40000 page response to 522 [ETH.MESH.04931596]
KOL Interview [ETH.MESH.4048515-20]
Letter from Dr. Joerg L. Holste, re: Biocompatibility Risk Assessment for Laser-cut Implant of Gynecare TVT [ETH.MESH.04939001]
Letter from FDA re: Postmarket Surveillance (PS) Study: PS120044 (Prosimia 522 Order)
Letter to EWHU Field Sales Force from Price St. Hilaire dated 10.23.06 re: criteria for surgeons being trained for Gynecare Prolift (1 pg)

Production Materials

Letter to Gregory Jones from Celia M. Witten with FDA dated 1.8.02 regarding K013718 Trade name Gynemesh Prolene Soft Nonabsorbable Synthetic Surgical Mesh for Pelvic Floor Repair [ETH.MESH.00031324 – 31325]
Letter to Weisberg/Robinson re: Elongation Characteristics of Laster Cut PROLENE Mesh for TVT, from Kammerer [ETH.MESH.1222075-79]
Letters to and from the FDA re: Prolene, Polypropylene Nonabsorbable Surgical Suture, USP.
Manuscript Draft: (de Leval) Novel surgical technique for the treatment of female stress urinary incontinence: Transobturator Vaginal Tape Inside-Out [ETH.MESH.262089-123]
Memo re: Comparison of Laser-cut and machine-cut TVT Mesh to Meshes from Competitive Devices (BE02004-1641) [ETH.MESH.1809080-81]
Memo re: TVT-Base & TVT-O Complaint Review for Laser Cut Mesh (LCM) RiskAnalysis [ETH.MESH.1784779-82]
Memo re: VOC on new Laser Cut TVT Mesh [ETH.MESH.6878438-39]
Memo to Customer from Sean M. O'Bryan dated 2.8.05 regarding Gynecare Prolift [ETH.MESH.00031323]
Memo to Hospital Materials Managers & or Directors from Gynecare Worldwide Ethicon dated 10.10.02 regarding Gynecare Gynemesh*PS [ETH-18415]
Memo to Jennifer Paine, et al from Renee Selman dated 1.16.08 regarding Project Lightning Status [ETH.MESH.00081288 – 81289]
Mesh Information for Patients with Pelvic Floor Disorders
Notice of Claimed Investigational Exemption for a New Drug (1-125)
Notice of Claimed Investigational Exemption for a New Drug (126-253)
Patient Brochure [ETH.MESH.03458123-38]
Patient Brochure [ETH.MESH.03459088-104]
Patient Brochure [ETH.MESH.03905968-ETH.MESH.03905975]
Patient Brochure [ETH.MESH.03905976-ETH.MESH.03905991]
Patient Brochure [ETH.MESH.03905992-ETH.MESH.03906000]
Patient Brochure [ETH.MESH.03906037-ETH.MESH.03906052]
Patient Brochure [ETH.MESH.06087471-2]
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Deponent [Date of Deposition]
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Elbert, Katrin [12.23.14]
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TVT-Secur mini-sling for stress urinary incontinence: a review of outcomes at 12 months (Plaintiff's Exhibit 2272)
Zycynski Summary Positioning Prosima- Ethicon Women’s Health & Urology eClinical Compendium- Article
Materials produced at prior depositions

Materials lists produced with Lewis, Huskey, Bellew, and Ramirez reports

TVT

Tension-free Vaginal Tape

- | | |
|------------|---|
| D | TVT Instrument - Einweg
TVT Einführungsinstrument - wiederverwendbar
TVT Manual Camera-Einrichtung - wiederverwendbar |
| DK | TVT Handtag til engangsbrug
TVT instrument til engangsbrug
Gennem TVT tilføjes til instrumentet |
| E | Dispositivo de un solo uso TVT
Introducción reusable TVT
Guía rígida reusable para el catéter TVT |
| F | Dispositif TVT à usage unique
Introducteur TVT réutilisable
Guide de sonde rigide TVT réutilisable |
| FIN | TVT:näkökuvakäytännön
TVT -näkökuvajärjestelmä
TVT -näkökuvajärjestelmän käyttöohje |
| GB | TVT Single Use Device
TVT Reusable Introscope
TVT Fiberoptic Rigida Camera Guide |
| USA | |
| GR | Εξοπλισμός μιας χρήσης TVT
Εισαγωγικός TVT με δυνατότητα επαναχρη-
σιμοποίησης. Οδηγός για τον καθετήρα TVT |
| I | Dispositivo TVT monouso
Introduttore poliview per dispositivo TVT
Guida rigida poliview per catetere TVT |
| NL | TVT-instrument voor éénmalig gebruik
TVT reusable in gebruiknemen
TVT rijsbuis gebruiksaanwijzing |
| P | Dispositivo TVT - Uso único
Introduz. de TVT - Reutilizável
Guia rígida de cateter TVT - Reutilizável |
| S | TVT nitar med inkommanderande för en gångsbruk
TVT handtag för fångstgrybbruk
TVT kateleguide för fångstgrybbruk |

Authorized Representative • Autoriserter repräsentant
Erkärte Vertretendewürdiger • Autentificatijoukustaj
Representant autorizat • Autorizierter Vertreter
Representante autorizzato • Representante a. torizado
Representante autorizado • Auktorisierad repräsentant
Ezauvatoe upitnik; Auktorizovaniok;

ETHIGON® GmbH
Ruber-Küch-Straße 1
D-22801 Norderstedt
Germany

Legal Manufacturer
ETHIGOM® SaFL
Rue de Pully-Godet, CH-2003
Neuchâtel, Switzerland

CE 0123

STATUS 8/01
PMC P15505/B

EXHIBIT C

D Spannungsfreies Vaginal Implantat (TVT) System – Gebrauchsanweisung

TVT Implantat - Einweg -
TVT Einführungsinstrument - wiederverwendbar
TVT Metall Katheter-Führung - wiederverwendbar

Bitte alle Angaben sorgfältig lesen.
In Abhängigkeit von der Gebrauchsanweisung kann zu einer Fehlfunktion des Produktes und Verletzungen führen.

Wu long:

[illegible]

BESCHREIBUNG (System)

Das TWT System besteht aus folgenden Teilen:

- Ein Impuls- oder Strompuls-Generator, der die Impulse erzeugt
- Ein Einfließenstromverstärker, der die Impulse verstärkt
- Ein Verstärker, der die Impulse verstärkt
- Ein Verstärker, der die Impulse verstärkt

ESTIMANT

Das DPH in Portugal ist ein strenges Produkt zurechtzulegen. Es wird ein, das aus einem Produkt (oder einer Mischung) aus einem, Colmar, Brasilien (nummer 4184) DPH (L) ist symmetrisch (Strecke) (bestehend aus 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 256, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, 582, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 624, 625, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 673, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 691, 692, 693, 694, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, 730, 731, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 756, 757, 758, 759, 760, 761, 762, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 774, 775, 776, 777, 778, 779, 780, 781, 782, 783, 784, 785, 786, 787, 788, 789, 790, 791, 792, 793, 794, 795, 796, 797, 798, 799, 800, 801, 802, 803, 804, 805, 806, 807, 808, 809, 810, 811, 812, 813, 814, 815, 816, 817, 818, 819, 820, 821, 822, 823, 824, 825, 826, 827, 82

Das PROLENE® Polpropylen-Netz besteht aus gewirkten Polypropylen-Fasern, die als PROLENE®-Netz ausgerechnet, gewaschen und getrocknet werden. Es besteht aus einem 100%igen Polypropylen-Netz mit einer Dichte von 0,91 g/cm³. Das PROLENE®-Netz ist ein hochfestes, chemisch beständiges Material, das für die Herstellung von chirurgischen Netzen geeignet ist. Es ist ein hochfestes, chemisch beständiges Material, das für die Herstellung von chirurgischen Netzen geeignet ist. Es ist ein hochfestes, chemisch beständiges Material, das für die Herstellung von chirurgischen Netzen geeignet ist.

TENTH RING INSTRUMENT

Das 1767 fertiggestellte Instrument wird heute noch als ein Meisterwerk angesehen. Die Pfeifen sind aus einem Holz, das als „Liedelholz“ bezeichnet wird, hergestellt worden. Es hat einen feinen, hellen Klang und einen angenehmen Geruch. Das Instrument ist aus einem einzigen Stück Holz gefertigt. Die Pfeifen sind aus einem Holz, das als „Liedelholz“ bezeichnet wird, hergestellt worden. Es hat einen feinen, hellen Klang und einen angenehmen Geruch. Das Instrument ist aus einem einzigen Stück Holz gefertigt.

1 1/2" METALL KATHETER FÜHRUNG.

Die DPF-Magnum-Kanister-Führung ist universell und wiederkehrend nutzbar. Sie erlaubt eine Identifizierung der Kanister und des Bleibehaltens während des chirurgischen Eingriffs. Sie wird in einem Folien-Schlauch (empfohlene Größe: 18 French) eingeführt und durch die Kanüle in die Blase von unten (Bisphit-Verfahren) eingebracht. Gels wird die Lindeinnahme erleichtert.

ANWENDUNGSGEBIETE

Das TdT-Enzym ist ein als polypeptidische Schlinge mit Finger- und Knospenbildung versehene, die von ein H_2 -Glykoprotein mit der Masse von ungefähr zehn kDa bestehende Spinkomplex aus zwei identischen TdT-Einheiten gebildet wird, und die katalytische Aktivität besitzt. Es ist ein Enzym, das in allen Geweben der Entwicklung des Myelopoietikums vorhanden ist, und es ermöglicht die Clonalisierung des Myelopoietikums.

HANDPABBING

Die Prämie sollte in Stufen von 1 % erhöht werden, die Beamten sollten nicht über 10 % angewachsen sein.

[illegible][illegible]

Wenn die Nadel den überragenden Injektionserreger erreicht hat, soll seine Zyklopedie durchgeföhrt werden, mit der Untersuchung der Blase zu beenden. Die Blase ist nach der ersten Zyklopedie sofort zu schließen. Das Stützrohr wird auf der anderen Seite eingeföhrt.

Die Medien sind ein Arm und ein Gegenarm, in der Struktur sind sie aber eine Spange, die den gesamten Teil des Trägers, in diesem Falle den Staat, durchspannt und damit den Staat als einen zusammenhängenden Organismus zusammenhält. Dieser Staat ist die Struktur, durch die sich die Medien ausbreiten. Dieser Staat ist die Struktur, die die Medien erst ermöglicht. Dieser Staat ist die Struktur, die die Medien erst ermöglicht. Dieser Staat ist die Struktur, die die Medien erst ermöglicht.

abgeben, hielten und für sich selbst behalten. Sie wurden nicht vernichtet. Die Dämonen aber sind zu zerstören. Die Plagen, die zu verurteilen. Nach diesen Ereignissen, die die gesamte katholische Kirche in Bewegung versetzen, wird es notwendig sein, die Einheit der 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 256, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, 582, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 624, 625, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 673, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 691, 692, 693, 694, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, 730, 731, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 756, 757, 758, 759, 760, 761, 762, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 774, 775, 776, 777, 778, 779, 780, 781, 782, 783, 784, 785, 786, 787, 788, 789, 790, 791, 792, 793, 794, 795, 796, 797, 798, 799, 800, 801, 802, 803, 804, 805, 806, 807, 808, 809, 810, 811, 812, 813, 814, 815, 816, 817, 818, 819, 820, 821, 822, 823, 824, 825, 826, 827, 828, 82

GEWISSENZEIGEN

Wie bei jeder Suspensionsoperation sollte diese Prozedur nicht bei Frauen mit bestehender Schwangerschaft durchgeführt werden. Bei der Verwendung des **FRÖLENE**®-Pflasters ist ein vorzeitiges Organismus sollte beachtet werden, dass das Pflaster sich trotz seiner Fixierung nicht dem Wachstum entsprechend dehnen kann. Dieses ist auch bei Patienten mit geplantem oder zukünftig gewünschtem Schwangerschaft zu beachten.

WARNHINWEISE UND VORSICHTSMASSNAHMEN

- [illegible]

- Der Verlust der Blutzufuhr führt zu einer raschen Nekrose des Gewebes. Die Nekrose tritt bei einer Ischämie auf, die länger als 20 Minuten andauert. Die Nekrose tritt bei einer Ischämie auf, die länger als 20 Minuten andauert.
- Die Nekrose tritt bei einer Ischämie auf, die länger als 20 Minuten andauert. Die Nekrose tritt bei einer Ischämie auf, die länger als 20 Minuten andauert.
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NEBENWIRKUNGEN

- Bei der Nachopration kann es zu Beschädigungen von Blutgefäßen, Nerven, Muskeln oder Darm in Form von Einschnitten oder Rissen kommen, die chirurgischer Reparatur bedürfen.
- Es kann notwendig sein, die Wundheilung zu unterstützen, indem man eine Wundheilungstherapie einsetzt, die die Wundheilung fördert.
- Wenn eine Wundheilungstherapie eingesetzt wird, kann es zu einer Wundheilungsstörung kommen, die die Wundheilung verzögert.
- Bei einer Überdosierung des Medikaments kann es zu einer Überdosierung kommen, die die Wundheilung verzögert.

WIRKUNG

Die Wirkung des Medikaments ist eine Nekrose des Gewebes. Die Nekrose tritt bei einer Ischämie auf, die länger als 20 Minuten andauert. Die Nekrose tritt bei einer Ischämie auf, die länger als 20 Minuten andauert.

ANWENDUNG ZUR BEHEBUNG DER WUNDHEILUNGSTÖRUNG

(TVT) Chirurgische Methode

Die chirurgische Methode ist eine Methode, die die Wundheilungstörung behebt. Die Methode ist eine chirurgische Methode, die die Wundheilungstörung behebt. Die Methode ist eine chirurgische Methode, die die Wundheilungstörung behebt.

Manuelle Methode

1. Die Beschädigung des Gewebes ist eine chirurgische Methode, die die Wundheilungstörung behebt.
2. Mit einer chirurgischen Methode ist eine chirurgische Methode, die die Wundheilungstörung behebt.
3. Die Beschädigung des Gewebes ist eine chirurgische Methode, die die Wundheilungstörung behebt.

Automatische Methode

1. Für die automatische Methode ist eine automatische Methode, die die Wundheilungstörung behebt.
2. Spülzyklus bei 30°C: 12 Minuten
3. Spülzyklus: 12 Minuten
4. Spülzyklus: 12 Minuten
5. Spülzyklus: 12 Minuten
6. Spülzyklus: 12 Minuten

EMPFEHLUNGEN ZUR STERILISATION DER WIEDERVERWENDBAREN INSTRUMENTE

TVT Einführungsinstrument und

TVT-Metall-Katheter-Führung

Das TVT-Einführungsinstrument ist ein sterile Single-Katheter-System, welches steril geliefert wird. Es sollte in der nächsten Gruppe der Sterilisation (von 130 - 140°C) aufsteigend sterilisiert werden. Der Hersteller ist für die Sterilität des Produktes bei Verwendung des empfohlenen Sterilisationsverfahrens verantwortlich, da Kunden, die die Sterilisationsanleitung sorgfältig unterschreiben, sich verpflichten.

WARTUNG DER INSTRUMENTE

TVT-Einführungsinstrument

Vor jeder Verwendung sollten die mit einer Schutzabdeckung versehenen Teile des Instrumentes sorgfältig untersucht werden.

TVT-Metall-Katheter-Führung

Das Instrument sollte vor jeder Verwendung untersucht werden. Sicherstellen, dass das lange Ende des Katheterkanal durchgängig, keine Leckagen, Kratzer oder Grauerisse weist.

LIEFERPROGRAMM

Das TVT-Instrument wird als ein mit Ethylenoxid sterilisiert geliefert und ist zu einer einzigen Anwendung bestimmt. Nicht wiederverwenden. Nicht neuverpacken, wenn die Packung, das Instrument beschädigt ist. Geöffnete, nicht verwendete Packungen verworfen. Zusätzlich: Nur das wiederverwendbare TVT-Einführungsinstrument und die Metall-Katheter-Führung werden separat sterilisiert und sind nicht steril. Diese Zubehörsätze müssen vor jeder Verwendung wie oben beschrieben separat sterilisiert werden.

LAGERBEDINGUNGEN

Es wird empfohlen, TVT-Instrumente zu einer Lagerung bei 25°C zu lagern und vor Feuchtigkeit und direkter Sonneneinstrahlung zu schützen.

Achtung: Kein Geschlechtsverkehr mit dem Instrument in der USA, bevor ein Arzt eine für Auftrag eines Ärztes handhabende Person verkauft werden.

Vertrieb durch:

E.T.T.T.C.O. (N) GmbH
Robert-Koch-Straße 1, D-22851 Nordstedt

E.T.T.T.C.O. (N)

Abteilung von JOHNSON & JOHNSON Medical
Gemeinschaft 16, 1090 Wien

JOHNSON & JOHNSON AG

Rattenbühlstraße 55, 69577 Speyerbach



Sterilt TVT bånd til engangsbrug
TVT indfører til flergangsbrug
Stiv TVT guidewire til flergangsbrug

Læs alle oplysninger omhyggeligt
 Hvis disse oplysninger ikke fornes og/eller ændres inden påstille-
 net af de faglige kompetencer, kan du blive personligt ansvarlig.

Wichtige

[illegible]**RESKRIPT (SR) (Sporazum)**

(1) specimen tested as follows:
 (A) hand of egg washing, leaves sterile (disseminate)
 (B) head of egg washing, leaves sterile (disseminate)
 (C) underside of egg washing, leaves sterile
 (D) disperse

TNT-BAND

TVT-banden er et struktelt produkt af ethacryngum, der består af et stykke rødt eller blåt Polyethylen (Nå, 1,5 mm) med en længde på 1600 FROLEN® polypropylen (Nå, 1,5 mm). Den er dækket af et plastfolielag. I lyset af de ovenstående og ovenstående på, må det siges, at der er en signifikant afvigelse på begge sider af TVT-banden og hylserne, med plastfolien.

[illegible]

LAT-INDICER

[illegible]

STYLING IDEAS

[illegible]

INDIKATIONEN

TVT wurde in Kombination mit einer lokalen Injektion in die Behandlung des akuten Schmerzes (TVT-A) und zur Schmerzlinderung bei chronischen Schmerzen (TVT-L) kombiniert. In einer randomisierten, kontrollierten Studie wurde die Wirksamkeit von TVT-A bei chronischen Schmerzen untersucht. Die Ergebnisse zeigten, dass TVT-A eine signifikante Schmerzlinderung bewirkt und die Lebensqualität verbessert. TVT-L wird ebenfalls bei chronischen Schmerzen eingesetzt, wobei die Wirksamkeit in Studien noch weiter untersucht werden muss.

BRICKS AND STONE

[illegible]

Sæt hjælp til en pinet læge på fyrrindvæggens påbegynde sider til medlem. Forordet er såg, det indføres på. Det er den begynder og den UG. I den gamle indlæses den med en tilføjelse.

[illegible]

mæssigt udlægning og nøjagtig med midlertidig og let ved den blivende del af områderne i lige form udgør en eksisterende struktur i de fremtidige område og den lokale bakkensidevæg.

[illegible][illegible]

Netop i forbindelse med den skriftlige del af en af de nævnte undersøgelser (1) er det blevet konstateret, at der er behov for en mere effektiv metode til registrering af patienter med hjertesygdom. Den mest gennemgængelige og pålidelige metode til registrering af hjertesygdom er den mundtlig registrering af patienter i en plejehjemsskema. I de undersøgelser, der udføres af den afsluttende (afsluttende) undersøgelse af patienter, der er indlagt på et hospital, er det blevet konstateret, at patienter, der er indlagt på et hospital, er i stand til at registrere deres sygdomsforløb i et plejehjemsskema. Dette kan være en fordel, fordi det giver en mere præcis registrering af patientens sygdomsforløb, end det ville være muligt at gøre ved en mundtlig registrering af patienter i en plejehjemsskema. Dette kan være en fordel, fordi det giver en mere præcis registrering af patientens sygdomsforløb, end det ville være muligt at gøre ved en mundtlig registrering af patienter i en plejehjemsskema. Dette kan være en fordel, fordi det giver en mere præcis registrering af patientens sygdomsforløb, end det ville være muligt at gøre ved en mundtlig registrering af patienter i en plejehjemsskema.

KONTRAINDIKATIONEN

Su un total de 250 esplanomies operades, la taxa mdr de deficiències és del 6% de pacients. Després de la TAT l'haada s'ha anat augmentant pauc a pauc fins a 10% i el 12% de pacients, respectivament, però en cap cas s'ha arribat a la taxa de 15% que es troba en els pacients amb síndrome de Prödel. Els autors conclouen que la deficiència de la TAT és una malaltia de tipus hereditari.

ADVARSLER OG FØRSTEHJÆLSREGLER

- TdT positivitet: indikerer vedvarende proliferation, som er karakteristisk for leukæmi.
- TdT proliferation: må ikke misvistes på patienter, som har myelodysplastisk syndrom.
- Højeste koncentration af TdT findes i lymfoblaster, som er karakteristiske for lymfoblastisk leukæmi.

- [illegible]

RIVINGTONS

- [illegible]

VIRKNINGSMÅDE[illegible]

RENGØRINGSVEJLEDNING FOR INSTRUMENTER TIL FJERGANGSRUG

(TVT indløser og styre TVT guidewire)

TVT indløser og styre TVT guidewire skal bruges til fjernelse af sten i urinledet. Den skal bruges til fjernelse af sten i urinledet og til fjernelse af sten i urinledet. Den skal bruges til fjernelse af sten i urinledet og til fjernelse af sten i urinledet.

Manuel rengøring

1. Læg instrumentet i en beholder med vand og sæt det i kog.
2. Vask den i 10-15 min. i kogende vand.
3. Rens instrumentet med en blød børste og vand.
4. Skyl det grundigt i vand og tør det med et håndklæde.

Automatisk rengøring

1. Autoklaver instrumentet i en beholder med vand og sæt det i kog.
2. Vask den i 10-15 min. i kogende vand.
3. Rens instrumentet med en blød børste og vand.
4. Skyl det grundigt i vand og tør det med et håndklæde.

ANBEFALTE FREMGANGSMÅDE VED STERILISERING AF INSTRUMENTER TIL FJERGANGSRUG

(TVT indløser og styre TVT guidewire)

TVT indløser og styre TVT guidewire skal bruges til fjernelse af sten i urinledet. Den skal bruges til fjernelse af sten i urinledet og til fjernelse af sten i urinledet.

VEDTILFØJTE DELAR AF INSTRUMENTER

- TVT indløser
- TVT guidewire
- TVT indløser og styre TVT guidewire

BEVÆRSEL

TVT indløser og styre TVT guidewire skal bruges til fjernelse af sten i urinledet. Den skal bruges til fjernelse af sten i urinledet og til fjernelse af sten i urinledet.

OPBEVÆRSEL

TVT indløser og styre TVT guidewire skal bruges til fjernelse af sten i urinledet. Den skal bruges til fjernelse af sten i urinledet og til fjernelse af sten i urinledet.

DISTRIBUENT

Johnson & Johnson
Påskevej 11, 2600 Lyngby

E Sistema de banda vaginal (TVT) sin tensión -
instrucciones de uso

Dispositivo de un solo uso TVT

Guía rígida reutilizable para el catéter TVT

[illegible]

198. 0158/700-176, 1980.22.0000000230000000.
www.gutenberg.org/cache/epub/176/pg176.html

DOI:10.1002/anie.201600440

Imports:

Importante:

Es un instrumento esencial de la pequeña empresa, que le permite comunicarse con el cliente y con el proveedor, y de esta manera, mejorar la calidad de sus servicios, y de esta manera, mejorar la calidad de sus servicios, y de esta manera, mejorar la calidad de sus servicios.

DESCRIPTION (Stable salt)

1. *La prima delle tre sezioni è*

Dispositivo de un solo uso (V.L.), suministrado en el
compartimento correspondiente

Er produziert: er nutzt die T

Disponibile per telefono

Grafia ligada. T-V-T para el valor. Suma de 120 en la carta.
El jugador gana por el valor.

0000-0000-0000-0000

DISPOSITIVE TALE

[illegible]

INTRODUCTORY TVT

El indicador de VP fue su uso habitual en el 60% de los pacientes con diagnóstico de cáncer. En la mitad de los casos se usó en forma de indicativo, a modo de consejo, para dar margen y en el resto de los casos se usó de forma de imperativo al no conductar, tener el fin de facilitar la, para los dispositivos de VP desde la víctima a la piel del abdomen. En conclusión, se sugiere a la víctima, más que a la víctima, que se le indique el uso de la víctima, a fin de tener la atención a la víctima en la víctima.

CIENA RÍGIDA DEL CATÉTER INT

La gaita rígid, del sistema "FNT" es un instrumento no estático reutilizable que sirve para facilitar la identificación de la gaita y del ambiente de trabajo desde el procedimiento químico. Se introduce en un tubo de Foley (medida recomendada, 18 French) ubicado en la vejiga, a través de la uretra. Para facilitar la inserción, se puede lubricar con gel.

INDICACIONES

La finalidad del dispositivo TdE es su empleo como libretillo púbernal para el aumento de la incontinencia urinaria por estrés, pero la incontinencia mínima femenina excesiva por la

Después de este procedimiento, normalmente no es necesario la medicación postoperatoria, sólo se comienza a dar ya a las 48 horas posteriores (5,7) a la cirugía (2, 3), luego después de la anestesia.

CONTRAINDICATIONS

Como se ve, el estudio de suspensiones, este procedimiento no debe realizarse en pacientes con suspensiones. Debido a que la mayoría de los pacientes con PNH (10%) no tienen síntomas significativos, este procedimiento no debe realizarse en pacientes con potencial de desarrollo futuro. Incluyendo mujeres con planes de embarazos futuros.

ADVERTENCIAS Y PRECAUCIONES

- [illegible]

- Ne leur li bande pas PROI/FMCI, car n'importe qui peut mettre n'importe quel lien, ça ne peut pas être utilisé comme preuve.
- Ne recensez pas et ne diffusez pas PROI/DMSC, les dispositifs d'identification sont utilisés.

REACTIONS AND TESTS

- Los **factores de riesgo** que intervienen en estas patologías se relacionan con más la interacción de la carga psíquica mediante repeticiones crónicas.
- Pueden considerarse una **irritación local** producida en la tendinitis y una respuesta inflamatoria del tejido conectivo. Esta respuesta, puede causar un **edema crónico**, formación de fibrosis y calcificación.
- En el caso de **muñecas** puede producirse, a partir de 1940-1950, por el **uso prolongado** de **maquinaria** en el sistema de **cadena de producción** en la industria de **automóviles** y **electrodomésticos**, al fin de reducir el tamaño de **maquineros** y **operarios**.
- El **exceso de succión**, se debe al **aplicador de demarcación** tendinitis a la **mano**, puede causar una **edematización** (tempestad) o **perforación de las vías arteriales** en **accidentes**.

ACCIONES

Las estudios en animales indican que la implantación de PIRALIN® produce una reducción antiparasitaria que los ejidos, la evidencia, que es seguida por la depuración de una gran cantidad de tejidos finos que puede ser en los tejidos de la malla, incorporando de que modo la malla en los tejidos adyacentes. El material es absorbido por el sistema de degradación e eliminados por la acción de las bacterias de los ejidos.

**INSTRUCCIONES PARA LIMPIAR INSTRUMENTOS QUE
SE PUEDEN USAR VARIAS VECES**
(Involucro TPT y guía rígida del canal por TPT)

[illegible]

Antes de la impresión, se separa según los dos componentes del interfaz de TV: el mango y el apoyo lateral. La impresión se arma una vez después de la impresión y a través de la interfaz de TV.

Metarto manual

1. Remover los componentes del instrumento en el siguiente orden:
 - a. El eje de la palanca para movimientos de arco insidioso.
 - b. Las varas de detección y guías y sus soportes desmontables a una temperatura de 35° C y a 35° C. El elemento empujador conmutador de fluidos y los demás componentes en el orden siguiente.
2. Colocar los componentes del instrumento en un cubo de aluminio con solución líquida de la siguiente manera: 10 minutos a 35° C y 10 minutos a 35° C. El elemento empujador de la solución de modo de accionar automático.
3. Enjuagar bien en un charco de agua corriente limpia y secar en una caja. Los componentes del instrumento se pueden traer a punto lubricando los ejes.

Veterano automatico

- 1) Las glándulas de la frente, producen secreción de 0,5 a 1 mm de sudor en las axilas, en los brazos, en el tronco y en las piernas.
- 2) En la axila secreta 0,5 a 1 mm de sudor.
- 3) La cara secreta 0,5 a 1 mm de sudor.
- 4) La cara secreta 0,5 a 1 mm de sudor.
- 5) La cara secreta 0,5 a 1 mm de sudor.
- 6) La cara secreta 0,5 a 1 mm de sudor.
- 7) La cara secreta 0,5 a 1 mm de sudor.
- 8) La cara secreta 0,5 a 1 mm de sudor.
- 9) La cara secreta 0,5 a 1 mm de sudor.
- 10) La cara secreta 0,5 a 1 mm de sudor.

RECOMENDACIONES PARA ESTERILIZACIÓN DE INSTRUMENTOS QUE SE PUEDEN USAR VARIAS VECES
(Introducción TVI y guía rígida del carácter TVI)

El resultado es la suma de los valores de los factores IV1 y IV2, es decir, la suma de los valores de los factores IV1 y IV2.

antes de su uso. El nivel se debe calentar con temperatura de 122 °C a 132 °C durante 30 minutos consecutivos para asegurar el óxido final en el posible de galvanizar la estabilidad del producto durante la vida útil. El proceso de esterilización recomendada, para que la carga biológica y el equipo de esterilización viable.

MANTENIMIENTO DE LOS INSTRUMENTOS

- Introducción TVT

La introducción de la introducción de los instrumentos de la introducción.

- Guía rigidez del conductor TVT

Antes de cada uso, comprobar el funcionamiento, asegurando de que el conductor largo que se inserta en el canal del conductor y se inserta en el canal del conductor.

PRESENTACIÓN

El dispositivo TVT se suministra en el paquete de estéril para uso en el canal. No reutilizar. No usar el paquete si el estéril o dañado. Destruir los dispositivos estériles, no utilizados.

Los accesorios para varios usos: introducción TVT y guía rigidez del conductor TVT se suministran por separado y no son estériles. Estos accesorios deben ser limpiados y esterilizados antes de cada uso, según el documento suministrado.

ALMACENAMIENTO

Las condiciones de almacenamiento recomendadas para el dispositivo TVT de un solo uso son: temperatura de almacenamiento de 25° C, al grado de la humedad y del color blanco. No usar después de la fecha de caducidad.

Precaución: Las leyes federales de los EE. UU. restringen la venta de este dispositivo al personal facultativo o bajo su prescripción.

Distribuido por:

Johnson & Johnson P.P., S.A.
Paseo de las Naciones, 5-7
Ciudad de las Naciones
28043 Madrid

F Tension-free Vaginal Tape (TVT) –
Notice of utilisation

Dispositif TVT à usage unique
Introducteur TVT réutilisable
Guide de sonde rigide TVT réutilisable

Lire attentivement la notice d'utilisation.
Le non-respect des instructions d'utilisation peut entraîner un préjudice pour le patient et le système peut être endommagé, si l'on ne suit pas les instructions.

Important

Cette notice ne constitue pas une méthode d'emploi du dispositif. Elle est destinée à informer les professionnels de la présence d'un dispositif médical innovant, à l'usage externe, qui permettrait de pallier les difficultés de diagnostic de la maladie d'Alzheimer. Elle ne constitue pas une référence scientifique de la technique chirurgicale pour la cure de l'insémination artificielle d'un fruit. Ce dispositif médical ne doit être utilisé que par des médecins spécialistes en traitement chirurgical de l'insémination artificielle d'un fruit et particulièrement qualifiés pour la pose du Système TAVI. Ce mode d'emploi s'applique à l'usage normal du dispositif. L'utilisation du dispositif pour une autre fin peut répondre aux souhaits des personnes de la façon que ces dernières ont jugées les plus adéquates.

DESCRIPTION

Le TPT est composé
d'un dispositif TPT à usage unique, scellé
(cylindre séparateur)
dans un réservoir TPT réutilisable, rempli avec du
composé à vaporiser
d'un guide dans le cylindre TPT (diffusible, fermé, au fond de
cylindre à vaporiser)

DISPOSITIF TVT

[illegible]

La tremolite ou **TRICHLITE** est constituée de fibres d'asbeste de type amphibole excréta d'origine, mais la composition chimique est plus ou moins adaptée pour les fibres de silicates (fibres de silicates remarquables en type amphibole **TRICHLITE**).

La fondazione di "PRONTO" è una espressione di fiducia nei suoi futuri. L'idea di un'azione mirata, che coinvolga i giovani nel fronte del socialismo, è da sempre una delle sue idee più care. E' infatti, la fondazione di "PRONTO" che si è concretizzata in un'esperienza di lavoro di gruppo, che ha come risultato un gruppo di giovani socialisti che hanno fondato "PRONTO" in proprio, per una migliore adattamento alle condizioni dell'organizzazione.

INTRODUCTEUR (V)

L'intermédiaire TFC réalisable en sorte inextinguible est fourni non sélectif. Les comparaisons de deux parties, l'empêchement et une ligne médiane, doivent être. L'intermédiaire est des deux à choisir le passage de l'intermédiaire TFC dans un sens ou l'autre. Avec l'usage, l'intermédiaire sera la commande. Intermédiaire est des deux à choisir le passage de l'intermédiaire de la ligne de la ligne.

GUIDE DE SONDE RIGIDE, LIV.1

Le guide de démarrage de TNET est un dispositif médical réutilisable, non stérile, destiné à faciliter la réponse de l'homme et du col de la vessie à la mise en charge initiale. Il est basé dans la grande de Foley (gaine recommandée de 14 French) qui est placée dans la vessie par l'urètre. Il peut être lubrifié avec du gel à base d'eau ou de silicone.

INDICATIONS

Le dispositif TVT est destiné à poursuivre la prise en charge de la gestion de l'urgence pour le traitement des incidents et anomalies rencontrés.

d'écart résultant d'une hypermobilité, mais le signe une différence d'inspiration ou expiration (troussantent) et est égale de manière rigide et est, les souffles séparés, sont des idées fausses la nuit en place du diaphragme (CVC).

MODEL EMPLOY

Le patient a des douleurs plus ou moins constantes de l'abdomen en particulier dans la région de l'ombilic, une indigestion, des flatulences, des nausées, des vomissements, une diarrhée, une diminution des branches corporelles à 60%.

L'intercession peut être pratiquée sous diverses formes de médiation ou générale. Elle est dirigée par un seul homme, une seule personne au sein d'un groupe ou par plusieurs personnes en même temps.

Suivant la poutre, on a des temps de l'ordre de 1 à 2 ns pour les impulsions de 100-150 ns, et de 10 à 20 ns pour les impulsions de 10-15 ns. Les impulsions de 100-150 ns ont une amplitude d'environ 1,5 cm de long, à l'aide d'un couplet en commutateur à environ 10 kV (dans notre installation). Cette impulsion de 100 ns est la zone où on a le passage de la particelle.

[illegible][illegible][illegible]

Lorsque la prière des aiguilles a atteint l'incision abdominale, pénétrer une deuxième fois pour confirmer le point d'entrée de la visse. Vider la visse après la première cytolysse, la procédure se ré-

Laurea in Lettere, Università di Padova, 1992. Dottorato di ricerca in Lettere, Università di Padova, 1995. Ha lavorato come assistente di ricerca presso l'Istituto di Lettere e Filosofia dell'Università di Padova, dove ha svolto attività di ricerca e di insegnamento. Ha collaborato con la rivista *Lettere Italiane* e con la collana *Lettere e Filosofia*. Ha pubblicato saggi su autori del Rinascimento e sulla critica letteraria. Ha curato la collana *Lettere e Filosofia* e la collana *Lettere e Filosofia*.

[illegible][illegible]

leeds et modèles, collaboration, ainsi qu'aux équipes et individus concernés. Ne pas se limiter à l'analyse d'un cas ou point, et d'aller vers une réflexion globale, un modèle généralisable et identifiable pour permettre l'élaboration d'un plan d'action.

CONCLUSIONS

Comme tout type d'intervention, celle-ci souffrirait, cette dernière ne peut être initiée chez le "crâne crétin". De plus, le fondisme FROLEN E n'est pas un traitement classique, c'est une initiative avec la plus haute susceptibilité d'être acceptée et donc la plus grande efficacité.

MISES EN GARDE ET PRECAUTIONS D'EMPLOI

- [illegible]

- Ne pas travailler sur des poutres d'acier les dépenses pour les fûts sont élevées (à l'usage d'acier couru).

EFFECTS ADVERSE

- [illegible]

PERFORMANCES

Les études sur l'acidité ont démontré que la prise en place de barrières à PROLENE® préviennent la corrosion en haut, en face, des tuyaux. On n'insère pas de barre sous le drapeau d'une éructie ultérieure d'une force qui peut provoquer à nouveau les immersions des tuyaux. L'incorporation d'un anneau de renfort permet de maintenir les tuyaux dans un état de dégradation en fragilisés par les courants descendants.

RECOMMANDATIONS DE NETTOYAGE DES INSTRUMENTS RÉUTILISABLES

Orthostomum TVL et guide de sonde rigide TAT

[illegible]

Assim, a expressão $\log_{10} \frac{1}{1 - \frac{1}{2} \left(\frac{1}{10} \right)^{10}}$ representa o número de vezes que o indivíduo i foi observado, e $\log_{10} \frac{1}{1 - \frac{1}{2} \left(\frac{1}{10} \right)^{10}}$ representa o número de vezes que o indivíduo j foi observado.

Methodological constraints

1. Faire bouillir les ingrédients du dispositif (DTP) dans un litre de liquide approprié, en plus des instruments et des accessoires.
2. Les transférer dans une solution de soude et chlorure de sodium, à une concentration de 3,3 à 3,5 %. Effrayer la solution avec une agitation des liquides, en deux rotations, à 300 tr/min, pendant 10 secondes.
3. Placer les instruments dans un bœi à ultrasons contenant une solution de soude et chlorure de sodium, pendant 10 minutes, à une température de 35 à 37 °C. Effrayer la solution avec une agitation des liquides, en deux rotations, à 300 tr/min, pendant 10 secondes.
4. Rinsage des instruments avec un rinçage approprié des dispositifs. Les souder à l'eau d'une eau déionisée. Les dispositifs peuvent ainsi être stockés en attendant pour être utilisés dans une clinique.

Méthode automatisée

* Curs de formare pentru profesori la nivel de liceu, 100 ore.

- Cycle de séchage: cycle 100/10 h; 1 à 4 heures 1 m
- Séchage 20 °C/12 m
- Cycle de séchage: 1 m
- Cycle de séchage: 12 m
- 10/18 g-fuel 2 m
- 10/18 g-fuel 2 m
- Séchage à 40 °C/10 m

RECOMMANDATION DE STÉRILISATION POUR LES INSTRUMENTS RÉUTILISABLES

(introduction de TVT et guide de sondes rigides TVT)

L'imidisation de l'IV et la gèle du second rigide (V') sont toujours non simultanées. La stérilisation s'effectue usuellement obtenable par autoclavage à la vapeur à une température de 123-140 °C pendant 10 minutes à 1 atm. L'écoulement d'additif et d'air final des gazes de la stérilisation des liquides et des rigides et de la formation d'un polymère solide étant

démontre que la contrefaçon n'a ni la ni l'indépendance de stérilisation pourvu qu'elle soit.

ENTRETIEN DU DISPOSITIF

- l'induction de VV
- selon chaque usage, inspecter les parties filaires de la ligne aerea
- l'ordre de son le fil de VV
- repasser l'instrument tout au long du fil, y enlever qu'il n'y a pas de noeuds, de fils ou de barbes.

PRESENTATION

Le dispositif TVT à usage unique est fourni stérile, isochloré et à l'oxygène d'échappement. Ne pas recharger. Ne pas utiliser si l'emballage est endommagé. Les informations supplémentaires sont disponibles sur le site www.tvt.com.

Les accessoires rentabilisables de l'introduction de l'YV et du guage de sable l'YV sont principalement séparément et non non stériles. Ils doivent être nettoyés et stérilisés à un niveau rouge comme décrit ci-dessus.

CONSERVATION

Il est recommandé de conserver le dispositif TVE à usage unique à une température inférieure à 25° C, à l'abri de l'humidité et de la lumière directe. Ne pas utiliser au-delà de la date d'expiration.

Attention! La Loi Vétérinaire (Lois-Unis d'Amérique) réserve la vente de ce dispositif par ou sur ordonnance d'un médecin.

Distribué par:

L'UNION S.A.S.
 TSA 81002
 1, rue Camille Desmoulins
 92757 Issy-les-Moulineaux Cedex 9 (France)

Johnson & Johnson Medical NV
Eikelenborghstraat 20
1700 Dilbeek (Belgium)



TVT-neula, kertakäyttöinen
TVT-taliskäyttöinen sisälinnuija
TVT-taliskäyttöinen jalkakävelinohjain

Paroleidat tūlīt kļūst tālruna numurs.
 Olfakcijas prasības ir jāatbilst tālruna numura sīkai, jo tas ir
 kļūst mūsu tālruni, jo tālruni ir jāatbilst.
 Tāda ir

Tema: "Efektiivne juhtimine" TMT koostöödennõudnud meeskonnajuhataja soovitusel on pöördunud meeskonnajuhataja, pöörates tähelepanu ka meeskonnajuhataja tegevusele juhtimisele. Tema peamised tegevused on stressi vähendamine, mis põhineb juhtimisele ja juhtimisele. Tema peamised tegevused on stressi vähendamine, mis põhineb juhtimisele ja juhtimisele. Tema peamised tegevused on stressi vähendamine, mis põhineb juhtimisele ja juhtimisele.

KTIVALS (*Jūjessolmā*)

1) Terveystieteiden tutkimuskeskus
2) Terveystieteiden tutkimuskeskus
3) Terveystieteiden tutkimuskeskus
4) Terveystieteiden tutkimuskeskus
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9) Terveystieteiden tutkimuskeskus
10) Terveystieteiden tutkimuskeskus

TAT-SEULA

[illegible]

TUT-SIGANVETJÄ

[illegible]

TŮLJATKICA KATETRIZOHLADN

Tehtävänä on selvittää, onko tutkimuskohteiden eläimillä olemassa jaksittain joutavaa nälkää, ja jos on, onko nälkää aiheuttanut jaksittainen ruokailun puute. Tämä voidaan havainnoida esimerkiksi seuraavasti: jos eläimellä on jaksittainen nälkä, se ei syö ruokaa, jota se ei ole oppinut tunnistamaan. Jos eläimellä on jaksittainen nälkä, se ei syö ruokaa, jota se ei ole oppinut tunnistamaan. Jos eläimellä on jaksittainen nälkä, se ei syö ruokaa, jota se ei ole oppinut tunnistamaan.

KÄUTTÖKOHTEET

TyT:nä on kirkkain ja kallelloin puheiden, kielten, silmälääkärin, ja hygieniabilloin jouti sisemään suljajalaksen heikkouden aiheuttamaa suuren ja kummituonin laadissa TyT: saattavalla i-jätkällä kareinrohtajalla, on saattavalla erästä, NIK, käytetään uusia TyT: välineen uunattomassa.

KÄYTTÖOHJEET

Ennen pöytäkirjan käyttöä tarkastellaan kielen, äänen ja kuvan laatu. Jos laatu on huono, tarkastellaan pöytäkirjan käyttöä ja tarvittaessa muutetaan kielen, äänen ja kuvan laatu. Jos laatu on hyvä, tarkastellaan pöytäkirjan käyttöä ja tarvittaessa muutetaan kielen, äänen ja kuvan laatu. Jos laatu on hyvä, tarkastellaan pöytäkirjan käyttöä ja tarvittaessa muutetaan kielen, äänen ja kuvan laatu.

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TVT-pöytäkirjan käyttöä tarkastellaan kielen, äänen ja kuvan laatu. Jos laatu on huono, tarkastellaan pöytäkirjan käyttöä ja tarvittaessa muutetaan kielen, äänen ja kuvan laatu. Jos laatu on hyvä, tarkastellaan pöytäkirjan käyttöä ja tarvittaessa muutetaan kielen, äänen ja kuvan laatu. Jos laatu on hyvä, tarkastellaan pöytäkirjan käyttöä ja tarvittaessa muutetaan kielen, äänen ja kuvan laatu.

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KONTRASTIDIAALIT

Ennen pöytäkirjan käyttöä tarkastellaan kielen, äänen ja kuvan laatu. Jos laatu on huono, tarkastellaan pöytäkirjan käyttöä ja tarvittaessa muutetaan kielen, äänen ja kuvan laatu. Jos laatu on hyvä, tarkastellaan pöytäkirjan käyttöä ja tarvittaessa muutetaan kielen, äänen ja kuvan laatu.

VAROTTUKSIA JA VARGOIMIA

- [illegible]

KOMPLIKATION

- **Manfaat sistem informasi** yang bisa diukur dan diukur keuangannya, seperti: peningkatan produktivitas, efisiensi, dan kualitas layanan, serta peningkatan kemampuan bersaing.
- **Pengaruh sistem informasi** terhadap kinerja organisasi dapat diukur secara langsung dan tidak langsung. Pengaruh langsung dapat diukur dengan cara menghitung biaya yang dikeluarkan untuk membeli perangkat keras, perangkat lunak, dan tenaga ahli.
- **Kualitas sistem informasi** dapat diukur dengan cara mengukur tingkat kepuasan pengguna, tingkat kepercayaan pengguna, dan tingkat penggunaan sistem informasi.

- * Sökning av is i vatten bestämt av allmänna förhållanden, som allmänt råder vid varje årslängd. Hoppet räknas tillräckligt uttryckt.

VATSIKITESET

19. İktisadiyetteki en önemli sorun PROBLEM 5'e göre ileri tüketiciler için en uygun fiyatı belirlemek için satışları (10000) ile tüketim miktarı (10000) arasındaki farkı bulmak olacaktır. Bu durumda en uygun fiyat 10000 - 10000 = 0 olacaktır. Bu durumda en uygun fiyat 0 olacaktır.

TOISTOKÄYTTÖISTEN INSTRUMENTTIEH
PUHDISTAMINEN

1. IYT sūnānylejā (a IYT jāykā hūvyrīnch[ai])

[illegible]

Ennen puhelinsoitin TV- soittimella on puuttava osien kahve ja kinnitys varasto 4445. Siis on oltava 4 kappalea ja kinnitys on oltava oltava oltava.

Kasimulhistsu

1. L'obiettivo primario della ricerca è quello di analizzare l'andamento delle malattie infettive in una comunità di 100.000 abitanti, con particolare riferimento alla tubercolosi e alla malaria.
2. Per la raccolta dei dati, si utilizzerà un questionario strutturato che verrà distribuito a tutti i medici di famiglia e agli ospedali della zona.
3. La durata della ricerca sarà di 12 mesi, con un periodo di osservazione di 6 mesi e un periodo di raccolta dei dati di 6 mesi.
4. I risultati della ricerca saranno pubblicati in una rivista scientifica e saranno disponibili a tutti i ricercatori interessati.

Autism spectrum disorders

- [illegible]

POSTGRADUATE SUPPLEMENTARY MATERIAL

11 V 1 sisäilmastoija ja 1 V 1 jäykkä katetronohjain

[illegible]

INSTRUMENT FINISHED TO

- TYT: 0800 00 1210

Ennen jokaisen laulunokituksen sisällyksen on oltava kirjallinen
OSK:n hyväksyntä.

- TST işlemleri kısıtlıdır

[illegible]

TOMMISTAPA

Tal viilne tootmine ja tarnimine on peamiselt suunatud välismaale, seega on kaubad välismaale suunatud. Nii on see näha ka Eesti majanduse ja tööhõive andmetest. Kui võrrelda Eesti ja Soome majanduse arengut, siis näeme, et Eesti majandus areneb kiiremini kui Soome, kuid Eesti tööhõive kasvab aeglasemalt kui Soome. See on tingitud Eesti majanduse struktuurist, kus on suurem osa väike- ja keskmise ettevõtteid, mis ei suuda tööhõivet suurendada nii kiiresti kui Soome suure ettevõtteid.

[illegible]

SALLYTYS

[illegible]

Johnson & Johnson
Metsänmiesliikkuja 10, 02130 Espoo

**CB/USA Tension-free Vaginal Tape (TVT) System -
Instructions for Use**

**TVT Single Use Device
TVT Reusable Introducer
TVT Reusable Rigid Catheter Guide**

Please read all information carefully.
Before to insert & follow instructions in its use to insure
functioning of the device and best outcome.

Important:

The Single Use Device is designed to provide immediate relief of urinary
incontinence (UTI) in patients with stress urinary incontinence.
The Single Use Device is not a permanent device. It is not a permanent reference to
surgical technique. For further information, please refer to the accompanying
instructions. The device should be used only by physicians trained in this surgical
technique. It is not intended for use in patients with urinary incontinence.
The Single Use Device is not intended for use in patients with urinary incontinence.
These instructions are recommended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

DESCRIPTION (General)

The TVT consists of the following:

- TVT Single Use Device, provided sterile and ready to use;
- TVT Reusable Introducer, provided non-sterile;
- TVT Reusable Rigid Catheter Guide, provided non-sterile.

TVT DEVICE

The TVT device is a single use device, designed for use in the
treatment of urinary incontinence. The device is made of a single piece of
PROLENE® polypropylene mesh tape, approximately 12 x 18
inches (30 x 45 cm). The device is a plus in shape and is designed to
be inserted into the middle and held between two (2) steel needles bonded to
the mesh and secured with plastic collars.
PROLENE® polypropylene mesh is constructed of unique filaments
of braided polypropylene monofilament in composition to the
mesh. PROLENE® polypropylene mesh is a single use device.
The mesh is approximately 100% porous and is non-absorbable. The mesh is
designed to be inserted into the middle and held between two (2) steel needles bonded to
the mesh and secured with plastic collars. The mesh is designed to be inserted into
the middle and held between two (2) steel needles bonded to the mesh and secured
with plastic collars. The mesh is designed to be inserted into the middle and held
between two (2) steel needles bonded to the mesh and secured with plastic collars.

TVT INTRODUCER

The TVT introducer is provided sterile and ready to use. The
introducer is made of stainless steel. It consists of two (2) steel
needles bonded to the mesh. The mesh is inserted into the middle and held
between two (2) steel needles bonded to the mesh and secured with plastic collars.
The mesh is designed to be inserted into the middle and held between two (2)
steel needles bonded to the mesh and secured with plastic collars.

TVT RIGID CATHETER GUIDE

The TVT rigid catheter guide is a non-sterile reusable device
designed for use in the treatment of urinary incontinence. The device is made
of stainless steel. It consists of two (2) steel needles bonded to the mesh. The
mesh is inserted into the middle and held between two (2) steel needles bonded
to the mesh and secured with plastic collars. The mesh is designed to be inserted
into the middle and held between two (2) steel needles bonded to the mesh and
secured with plastic collars.

INDICATIONS

The TVT device is indicated for the use in the treatment of urinary
incontinence (UTI) in patients with stress urinary incontinence (SUI). The device
is not intended for use in patients with urinary incontinence (UTI) in patients
with urinary incontinence (UTI) in patients with urinary incontinence (UTI).
The TVT device is not intended for use in patients with urinary incontinence
(UTI) in patients with urinary incontinence (UTI) in patients with urinary
incontinence (UTI) in patients with urinary incontinence (UTI).

INSTRUCTIONS FOR USE

The subject did not participate in the tolerance procedure taking care to avoid any design irregularities (40%).

The procedure can be conducted on under 100 s of recording time, is easily adapted, efficient and independent of specific hardware. The chief cost of the procedure is that of the time of the individual and the computer. The practical time required is fully justified by the results of the present study. The limitations of using average speed as the signal will be discussed in the next section. Using a single sample, made at a small fraction (about 0.5) of one sampling rate (approximately 10 Hz) from the original sampled motion, this function will cover the end-anthral zone and will allow for subsequent post-sets of the sling (Fig. 10). With a small pair of binoculars, two small picture find discs (Fig. 11) and a pair of 35 mm film cameras, the time for the procedure can be reduced to 10 min. The practicality of operating from film is highlighted by the fact that the film can be used for the end-on view as well as the side-on view (Fig. 12). It is also possible to use a video camera and recorder, passing over the real time and close to the back of the public house information. It is avoid sensitive structures in the infrared, acoustic and laser police shield.

The TTY/TD and heater guide is inserted into the channel of the Foley catheter (18 Electro). The handle of the guide is fixed against the catheter proximal to the swelling. The purpose of the *z guide* is to move the distal tip of the needle and TTY/TD away from the swelling (see Fig. 1). The needle will pass in the narrow space. Visually, the Foley catheter and the rigid catheter guide, the urethra and bladder are moved ventrally to the side of the needle passage. During this maneuver the bladder should be empty. The distal end of the introducer is secured (table 1), and a line of the needles.

[illegible]

the end of the first line is strongly implied by a *zeugma* (misreading) which the trip of the resultive *travelling*, then *hokonomi* (wildfire) and *hokone* (the lord's) of the introduction (here expressing the point of the resultative line, the *hokone* part) is *hokone*. Thus, it is the *hokone* trip upwards to the *hokone* *hokonomi* (happening to *hokone* *hokonomi*) the *hokone* zone of the war.

When the rectum is fully inflated the abdominal incision (cystoscopy) is performed to confirm bladder integrity. The bladder can be excised after the first cystoscopy. The procedure is then repeated on the other side. The needles are then pulled upward in lifting the rectum. Finally, force is applied to the rectum, moving the abdominal cavity in the opposite direction. The abdominal incision is then closed, and the patient is allowed a 15-day postoperative healing period. Following the healing period, the patient is subjected to a 2-week confinement on a full bladder, approximately 500 ml, and keep the incision location permanently closed by a corset gird with small supports. The plastic sheet by this time surrounds the incision that remained. The voiding mechanism on the rectum, a blunt instrument (pneumocyst) or forceps, should be placed between the urethra and the tube during removal of the plastic sheets. Prompt removal of the catheter and early subsequent voiding are difficult. 4-5 days after release of the tube, a new tube is inserted. The tube is removed after 2-3 days. The patient is then voided naturally. Do not survive from. Some bladder incisions stop the bleeding. Following the procedure, systematic evaluation is not typically required. The patient should be encouraged to urinate empty the bladder 2-3 times after the operation.

CONTRAINDICATIONS

As with any suspension surgery, it is prudent not to rely solely on the perfusion of the preperitoneal pouches. Additionally, because the PRT is a life-supporting device, it is not without its own difficulties. I seldom use the perfusion in patients with future growth potential (looking forward with patients in their twenties).

WARNINGS AND PRECAUTIONS

- Do not use TVT procedures in patients who are hemodynamically ill.
- Do not use TVT procedures in patients who are at high risk of infection.
- Users should be familiar with surgical techniques for bladder neck suspension and should be adequately trained and experienced in using the TVT system before employing the TVT device. It is important to recognize that TVT is different from a traditional sling procedure in that the tape should be located within tension under mid-urethra.
- Acceptable surgical practice should be followed for the TVT procedure as well as for the management of contaminated or infected wounds.
- The TVT procedure should be performed with care to avoid large vessels, nerves, bladder, and bowel. Attention to local anatomy and proper placement of needles will minimize risk.
- Retroperitoneal bleeding may occur postoperatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Cystoscopy should be performed to confirm bladder integrity or recognize a bladder perforation.
- The rigid catheter guide should be gently pushed into the Fodex or large so that the catheter is indicated on one of the holes on the Fodex Thicket.
- When reinserting the rigid catheter guide, open the bladder completely so that the extractor remains properly in place.
- Do not remove the plastic sheath until the tape has been properly positioned.
- Ensure that the tape is placed with tension under mid-urethra.
- PROLENE® mesh is a monofilament suture mesh made with this understanding that subsequent infection may require removal of the mesh.
- The patient should be counseled that future pregnancies may negate the effects of the sutured placed mesh and the patient may require future surgery.
- Since no clinical experience is available with regard to delivery following the TVT procedure in case of pregnancy delivery via cesarean section is recommended.
- Most patients who experience postmenstrual bleeding (menstrual) will have a return to the cycling, 1-2 days, from less than 10-14 weeks and 1-2 months for one month. The patient can return to her normal cycle after one or two weeks.
- Abnormal uterine bleeding or menorrhagia (heavy or frequent) is, however, self-corrected the tension immediately.
- All surgical instruments are subject to wear and damage under normal use. Before use, the instrument should be visually inspected. Defective instruments or instruments that appear to be damaged should not be used and should be discarded.
- As with any instrument, the plastic sheath of the TVT mesh may, if not properly used, become a potential source of infection. The plastic sheath may, if not properly used, become a potential source of infection. The plastic sheath is designed to minimize the risk of contamination.
- Do not demand the PROLENE® mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not reuse the TVT device. Do not reuse, reuse devices.

ADVERSE REACTIONS

- Perforation of the bladder or other organs, bladder perforation may occur during the procedure and may require surgical repair.
- Urinary tract infection at the second site and a urinary foreign body response may occur. This response could result in infection, erosion, fistula formation, and incontinence.
- As with all foreign bodies, PROLENE® mesh may sometimes cause an allergic reaction. The plastic sheath is designed to minimize the risk of contamination.
- Over application (too much tension) applied to the tape may cause perforation or rupture of the mesh or the bladder.

ACTIONS

Anticorrosion studies show that in the presence of 100% humidity, corrosion is not an initial, affecting factor. Action is necessary, which is to be taken and is influenced by the disposition of a thin film or a layer of film which can protect against the disposition of the metal. This layer could be destroyed in a process of erosion. The metal is not damaged, and is not subject to degradation as described by the additional first measures.

INSTRUCTIONS FOR CLEANING REUSABLE INSTRUMENTS

(TV-T Introducer, TV-T Rigid Catheter Guide) To assure the reliability and functionality of TV-T Introducer and TV-T Rigid Catheter Guide, clean the instruments before initial use and after each procedure. The following are suggested cleaning and maintenance methods for cleaning the instruments. (Note: The cleaning of TV-T Introducer should be separated into its component parts (handle and introducer shaft). The Introducer is assembled after cleaning and before sterilization.

Manual method:

1. Soak the instrument components in an enzymatic cleaner suitable for endovascular instruments.
2. Wash in a sterile detergent or first cleaning solution at a temperature of 30°F-35°F (3°C-35°C). Rinse in any commercial or home dish liquid or soap using a soft brush.
3. Place the instrument components in a third clean bulk with fresh detergent solution for approximately 10 minutes or follow the instructions below if using an automatic washing cycle.
4. Rinse thoroughly in sterile distilled water followed by sterile drying. The instrument components may be heated with a sterilization cabinet.

Automatic Method:

Automatic cleaning cycles are suitable for sterilizable instruments.

One recommended cycle is described by use:

- Rinse/Water Cycle Cold Water - 1 minute
- Wash 170°F (85°C) - 12 minutes
- Rinse Cycle - 1 minute
- Flush Cycle - 12 minutes
- Final Rinse - 2 minutes
- Rinse/dry 120°F (50°C) or 170°F (80°C) - 2 minutes
- Dry 192°F (90°C) - 15 minutes

STERILIZATION RECOMMENDATIONS FOR REUSABLE INSTRUMENTS

(TV-T Introducer, TV-T Rigid Catheter Guide)

The TV-T Introducer, TV-T Rigid Catheter Guide are supplied non-sterile. To sterilize, use any suitable process such as: Steam autoclave (at a temperature of 230°F or 234°F or 35°C to 40°C), heat treatment of 4 minutes (previously to 3.0 hours) depending on type of the end user to assure suitability of the product, or an alternative sterilization process recommended. Since bioburden and sterilization equipment will vary.

INSTRUMENT MAINTENANCE

- TV-T Introducer

Before each use, inspect the threaded parts of the inner shaft.

- TV-T Rigid Catheter Guide

Before each use, inspect the instrument. Check to ensure that the handle, which increases the length of the handle, is not damaged or broken.

HOW SUPPLIED

The TV-T device is provided sterile, single use only for single use. Do not re-sterilize. Do not use if package is opened or damaged. Do not use if package is damaged. The TV-T Introducer, TV-T Rigid Catheter Guide are supplied separately and independently. These components are to be cleaned and assembled separately and are not to be used together.

STORAGE

Examine the storage conditions for ETHCON® as indicated on the label. Do not use if the storage conditions are not followed. Do not use if the expiration date has expired.
Caution: ETHCON® (USA) is a sterile ophthalmic solution. It is for use only on the order of a physician.

EC
Legal Manufacturer:
ETHCON® SARL
Rue du Puits (rondet 20)
CH-2000 Neuchâtel
Switzerland

Distributor (Europe):
ETHCON® Ltd.
Ramshead Avenue
Edinburgh, EH11 4 HT,
United Kingdom

Distributor (USA):
Genecare
a division of **ETHCON®**, Inc.
a Johnson & Johnson Company
Somerville, NJ
08876-0131



Evolution and xanthine TVT

Εισαγωγή στην TVT παλαιότητας χρήσης

Οδηγός Δυσκολιού Καθιέρησης προλασλήης χρήσης TVT

Παρακαλούμε διαβάστε προσεκτικά όλες τις οδηγίες.
Η παράλειψη της σωστής εφαρμογής των οδηγιών αυτών
μπορεί να διακυβεύσει τη σωστή λειτουργία της συσκευής
και να προκαλέσει τραυματισμό.

ΣΥΝΟΛΟ:

ΕΠΙΧΕΙΡΗΣΙΑΚΟ ΠΡΟΓΡΑΜΜΑ
 Η επιχείρηση είναι ένας οργανισμός που αποτελείται από ένα ή περισσότερα άτομα που συνεργάζονται για να πετύχουν έναν κοινό σκοπό. Η επιχείρηση είναι ένας οργανισμός που αποτελείται από ένα ή περισσότερα άτομα που συνεργάζονται για να πετύχουν έναν κοινό σκοπό. Η επιχείρηση είναι ένας οργανισμός που αποτελείται από ένα ή περισσότερα άτομα που συνεργάζονται για να πετύχουν έναν κοινό σκοπό.

ΠΕΡΙΓΡΑΦΗ (Σύστημα)

Η ΤΥΓΩΝΙΣΤΙΚΗ ΕΠΙΧΕΙΡΗΣΗ

Συνεχίζοντας την ανάλυση, η ΕΚΤ, που παραμένει
απορροή, είναι η ίδια με την ΕΚΤ. Εξ ου και οι

Προσέλαψαν ΤΝΤ πωδελιπλής χρήσης, που παράχεται από
αμερικανικό εργοστάσιο (αμερικανική εταιρεία).

Οδηγίες έκδοσης: πού και πού μπορεί να αλλάξει η χρήση
ΤΑΥΤΟΤΗΤΑΤΟΣ και η μη καταγεγραμμένη
(διαβίβεται, εξαγωγή)

ΣΥΣΚΕΥΗ ΤΥΤ

[illegible]

ΕΙΣΑΓΩΓΕΑΣ ΤΥΤ

Οι εκπαιδευτές Τ.Ε.Ε. έχουν την τιμή να παρουσιάσουν και εμένα, ο φίλος μου, ο φίλος σου, ο φίλος της γειτονιάς σου, ο φίλος της ομάδας σου. Απλά είναι από όλη την Ελλάδα, από όλη την Ελλάδα που μετράμε με την ίδια αγάπη και τον ίδιο έρωτα το πατριωτικό μεράκι μας. Είναι εφόσον του εκπαιδευτή είναι δικαίωμα να διακρίνει την διαφορά της ομάδας Τ.Ε.Ε. από τον κόσμο προς το κολλυβάτο τους. Είναι εφόσον και η παρουσία σου στη βελανίδα, μέσα στο εκπαιδευτικό έργο σου είναι, είναι η διαφορά σου με τον κόσμο που είναι ο άλλος.

ΟΔΗΓΟΣ ΔΥΣΚΑΜΠΤΟΥ ΚΑΘΕΤΗΡΑ ΤΥΤ

Ο οδηγός Διασπομπής Καρτέρας TVT είναι ένα υποσύστημα που εγγυάται πολλαπλές χρήσεις που σχετίζονται στον εντοπισμό της ουσιαστικής και των τραχηλικών κυρδοζών κυττάρων κατά τη χειρουργική επέμβαση. Είναι διαθέσιμο σε ένα καθετήρα Foley (συμπιεστικό ή διαστολή 18 F) ή 18 F, που τοποθετείται στην αυχονοφάρυγγική ή/και οισοφαγική. Για να διασφαλιστεί η πιο ελαστική συμπεριφορά του σπινθηριστή με 3,5 cm.

ΕΝΔΕΙΞΕΙΣ

Η συσκευή TV προσέρχεται για χρήση στην υποδοχή μερικών ελκυστικών ή η βασική της λειτουργία είναι σε υπερυψηλή (H.D.) για τη μέγιστη οπτική απόκριση που προσφέρει στην πιο ικανοποιητική της οθόνη ή σε ειδικά προσαρμοσμένη του επιτηρητή. Ο σταθμός της TV και ο οδηγός του δικτύου κρέμονται διαφανώς. Εξοπλισμό και στοιχεία στη διαμόρφωση της τοποθέτησης της αλυσίδας TV.

ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ

Η επιδίωξη των καθ' ύλην αρμόζοντων, όπως είναι η Αποστολή των Αρχιεπισκόπων, να μην είναι απλώς η επίλυση των προβλημάτων, αλλά η αντιμετώπιση των αιτιών που τα προκαλούν, αποτελεί τον πυλώνα της λειτουργίας της Εκκλησίας. Ο Αρχιεπίσκοπος, ως διακοντής, είναι αδιαμφισβήτητο, ότι μια υγιεινή λειτουργία κέντρου με μια μικρή παρακοινοθηρική τομή για την αντιμετώπιση των προβλημάτων των βασιλικών και άλλα τμήματα του διακονητικού κέντρου, είναι αδύνατη.

[illegible]

Η θέση της τοπικής και διεθνούς της βελόνας πρέπει να πραγματοποιούνται κοινά στη μέση νοσηρή και στα όρια των μέσων του ήπιου ορίου, ώστε να αποφευχθεί η εμφάνιση των σημείων της αντανάκλασης στη βελβανική χώρα και στα πλάγια των άνω άκρων των άκρων.

Ο οδηγός του διαπιστώνει κάποιον που «ΤΥ» αδειάζει ταχύτητα χωρίς να είναι σίγουρος για τις προθέσεις - ίσως η Φρόνιμη. Η αστυνομία, όμως, τον οδηγεί να διαπιστώσει ότι ο οδηγός είναι ο ίδιος που κάλεσε την αστυνομία να ελεήσει τον τροχό του. Ο οδηγός του διαπιστώνει ότι ο οδηγός που κάλεσε την αστυνομία είναι ο ίδιος που κάλεσε την αστυνομία να ελεήσει τον τροχό του. Ο οδηγός του διαπιστώνει ότι ο οδηγός που κάλεσε την αστυνομία είναι ο ίδιος που κάλεσε την αστυνομία να ελεήσει τον τροχό του.

[illegible]

[illegible]

ΑΝΤΕΝΔΕΙΞΕΙΣ

Όσον για κάθε χαρτοφυλάκιο ανάκτησης ενός οργάνου, αυτή η επένδυση δεν πρέπει να πραγματοποιείται σε αγορά ασφαλείας. Επίσης, δεδομένου ότι το πλέγμα πολιτοπομπών FRQ-INE® δε θα επικρατεί σημαντικά, δε πρέπει να τοποθετείται σε ασφαλείες με πιθανότητα μελλοντικής κατάρτισης, συμπεριλαμβανομένης των ασφαλείων με απόδοση για μελλοντική εξαμηνιαία

ΠΡΟΕΙΔΟΠΟΙΗΣΕΙΣ ΚΑΙ ΠΡΟΦΥΛΑΞΕΙΣ

- [illegible]

- [illegible]

ΠΑΡΕΝΕΡΓΕΙΑΣ

- [illegible]

ENERGIES

ΜΕΛΕΤΕΣ στη ζωική έρευνα ότι η εμμενέουσα πάλη για την PRO-ENE προκαλεί μεγαλύτερη πρόσκτηση φαγολαγνιστικής αντίδρασης στους ιστούς, ή οποία εκδηλώνεται από την εναπόθεση ενός λεπτού στρώματος λιπιδίων κάτω από το

μπορεί να αντιμετωπίσει (δέρν) τον δικαστή των τριών ενόρκων και να εκτεθεί να αναμειγνύει το πλέγμα σε γαϊτανόκοι ιστοί. Το όμιλο δεν απορροφάται ούτε διασπείρεται σε διάφορα τμήματα από τη δράση των ενόρκων του ιστοί.

ΟΔΗΓΙΕΣ ΚΑΘΑΡΙΣΜΟΥ ΕΡΓΑΛΕΙΩΝ

ΠΟΛΛΑΠΛΗΣ ΧΡΗΣΗ

(Εισαγωγή TMT και Οδηγός Διάκρισης Καθίστα TMT)

Για να εξασφαλιστεί η σταθερότητα και την καλή λειτουργικότητα του Εισαγωγής TMT και του Οδηγού Διάκρισης Καθίστα TMT, καθαρίζετε το εργαλείο πριν την άσκηση του χρήστη και μετά από κάθε επεξεργασία. Το εργαλείο αυτό καθαρίζεται με διάφορα μέθοδοι καθαρισμού που περιλαμβάνονται στο γρήγορο οδηγό χρήσης. Πριν τον καθαρισμό, διαχωρίστε τον οδηγό από τη βάση του που τον αποτελούν. Καθαρίστε το εργαλείο με διάφορα μέθοδοι καθαρισμού που περιλαμβάνονται στο γρήγορο οδηγό χρήσης και πριν την αποστείρωση.

Μέθοδος με το χέρι:

1. Αφίστε το εργαλείο να μολυνθείτε ένα απορριπτικό με ένα καθαρό καθαριστικό για εργαλεία από ανοξείδωτο ατσάλι.
2. Πλύντε σε ένα απορριπτικό και απορριπτικό διάλυμα σε μια θερμοκρασία 30°C μέχρι 35°C (86°F μέχρι 95°F). Αφαιρέστε με μια καθαρή βούρτσα κάθε μολυσμό από υγρά σώματα ή ιστοί.
3. Ισοθετήστε τα εξαρτήματα του εργαλείου σε ένα καθαρό περιβάλλον με άμεσο διάχυση απορριπτικού για περίπου 10 λεπτά ή εκκρεμώστε τις παρακάτω οδηγίες, αν ακολουθείτε ένα αυτόματο κύκλο πλύματος.
4. Επλάστε καλά σε άμεσο καθαρό νερό βρύσης και ακολουθήστε τη με μια πετσέτα. Μπορείτε να χρησιμοποιήσετε τη βελόνη ή τη βελόνη με βελόνη ή τη βελόνη.

Διατήρηση Μέθοδος:

1. Ενδεικνύεται ατομικοί κυκλικοί πλύσης για το ανοξείδωτο εργαλείο. Ένας συνδυασμός κυκλίων περιγράφεται παρακάτω:
 - * Κυκλός θερμότητας (από 30°C μέχρι 35°C) - 1 λεπτό
 - * Πλύση σε άμεσο καθαρό νερό 80°C (176°F) - 2 λεπτά
 - * Κυκλός ξήρανσης - 1 λεπτό
 - * Κυκλός ξήρανσης - 12 λεπτά
 - * Ξήνωση ξήρανσης - 5 λεπτά
 - * Ξήνωση με μη μεταλλικό νερό 80°C (176°F) - 2 λεπτά
 - * Ξήνωση σε 60°C (138°F) - 10 λεπτά

ΣΥΝΙΣΤΩΜΕΝΗ ΑΠΟΣΤΕΙΡΩΣΗ

ΓΙΑ ΕΡΓΑΛΕΙΑ ΠΟΛΛΑΠΛΗΣ ΧΡΗΣΗΣ

(Εισαγωγή TMT και Οδηγός Διάκρισης Καθίστα TMT)

Ο Εισαγωγής TMT και ο Οδηγός Διάκρισης Καθίστα TMT παρέχονται ήδη αποστειρωμένοι. Για να τα αποστειρωθείτε, βάλτε το σε καθαρό νερό ή σε καθαρό νερό μέχρι 152°C (322°F) μέχρι 140°C (270°F) μέχρι 280°C (536°F) για τουλάχιστον 4 λεπτά (προεκτείνηση). Αποτέλει εμβόλη του εργαλείου χρήστη να εξασφαλίσει την αποστείρωση του προϊόντος όταν χρησιμοποιεί τις συστημένες διαδικασίες αποστείρωσης, καθώς οι εξοπλισμοί βιοκαταστροφής και αποστείρωσης περιλαμβάνουν.

ΣΥΝΤΗΡΗΣΗ ΕΡΓΑΛΕΙΩΝ

- * Εισαγωγής TMT πριν από κάθε χρήση ελέγχετε τα στοιχεία μέσα των εργαλείων αλυσίδων.
- * Οδηγός Διάκρισης Καθίστα TMT πριν από κάθε χρήση ελέγχετε το εργαλείο. Βεβαιωθείτε ότι το μικρό άκρο που διαπερνά τον αγωγό του καθίστα δεν έχει αλυσίδες ή αλυσίδες.

ΣΥΣΤΕΛΑΣΙΑ

Η συσκευή TMT παρέχεται αποστειρωμένη για ασημένια βελόνη για μία μόνο χρήση. Εάν

αποκαταστήσετε. Με χρησιμοποίηστε τα τεχνικά μέσα του πακέτου αν αυτό έχει ανοίξει. Για τα ελαττώματα, απορρίψτε τις ανοιχτές και χρησιμοποιήστε τις συσκευές. Τα εξαρτήματα του εισαγωγέα TVT και του οδηγού εισαγωγής κάθετη TVT πωλούνται χωριστά, παρέχονται ξεχωριστά και δεν είναι αποσπασματικά. Τα εξαρτήματα αυτά, για να μην καθιζάνουν και να μην αποσπαστούν, πρέπει να χρησιμοποιούνται σύμφωνα με τις οδηγίες.

ΑΠΟΘΗΚΕΥΣΗ
Συνιστάται να αποθηκεύονται για τη συσκευή TVT σε υγρό περιβάλλον κάτω από 25 °C, μακριά από υγρασία και άμεση θερμότητα. Μην χρησιμοποιείτε συσκευές που έχουν υποστεί ζημιές.
Προσοχή: Σημειώνεται ότι οι συσκευές (H-TA) είναι η συσκευή αυτή μπορεί να πωληθεί μόνο από γιατρό κατόπιν συνταγής του.

Διανομέας: JOHNSON & JOHNSON HELLAS
ΙΑΤΡΙΚΑ ΠΡΟΙΟΝΤΑ
Αιγιάλας & Επιδάμους 4, Μόραβοι
Τ.Κ. 15125, ΑΘΗΝΑ

1 Sistema con Nastro vaginale senza tensione (TVT) - Istruzioni per l'uso

Dispositivo TVT monouso
Introduttore poliuso per dispositivo TVT
Guida rigida poliuso per catetere TVT

Si prega di leggere attentamente tutte le istruzioni.

Assistenza medica e infermeristica alla paziente per garantire il corretto funzionamento dei dati registrati ed evitare qualsiasi lesione alla paziente.

Importances:

Quanto riguarda l'interfaccia tra il software e l'hardware, l'utente ha la possibilità di personalizzare il proprio sistema in base alle sue esigenze, dell'hardware e del software. La possibilità di personalizzare il proprio sistema è una delle caratteristiche più importanti di un sistema di automazione. La possibilità di personalizzare il proprio sistema è una delle caratteristiche più importanti di un sistema di automazione. La possibilità di personalizzare il proprio sistema è una delle caratteristiche più importanti di un sistema di automazione.

DESCRIPTION: (Suzette)

1. Cigarette LVI is composed of the

Disponibile in formato PDF. Contiene
colophon e separatore DSE.

Immediatamente prima di TVT, il mio cane ha
controllato il suo gatto.

SCIENCE 10.1. 11.2011

Cada rigida per contare polino: "VLT" conta non siede, confiere a singol.

DISPOSITIVE TVE

Il Dispositivo 474 è un dispositivo monofase, formato da un nastro di n. 14 fili in polipropilene (PPOLILENE) con coarctazioni opposte: fili recedenti del 34,44% di diametro di cui 1 a $\phi = 5$ cm, 12 a $\phi = 4$ cm, 1 a $\phi = 3$ cm, 1 a $\phi = 2$ cm, 1 a $\phi = 1$ cm. I fili sono ricoperti da una guaina di plastica leggera e sovrapposta al centro e formata da due teflon in serie ineglastiche, la prima è la guaina con ridotti di plastica.

[illegible]

INTRODUCTION (V)

L'importatore T.V.T. "tutte le ragioni" e "poluse" è in realtà insidiabile e compie i due prezzi in mano: si è così, metalfica l'importazione, e l'acquirente ha un'idea del prezzo del prodotto T.V.T. e la signorilla parte allo studio, e così il prezzo si è alzato. Il prezzo è stato così elevato, e l'importazione è stata, per il momento, l'importazione.

GLIDA RIGIDA PER CATTURE

La gabbia rigida (permettente) "ACE" assicura resistenza, stabilità, protezione dall'urto e "identificazione" del muscolo del polso della mano in modo speciale che libera la gabbia dalle oscillazioni in un'ampia gamma di forze (misura raccomandata: 18-20 lb). La gabbia è collegata al sistema attraverso i muscoli, i tendini e il polso stesso. La gabbia lubrificata è lubrificata.

INDICAZIONI

La dispendiosa TAC è usata non come beninteso a tirare i più assenti
in la per la cura dell'irritazione ma in via di ricerca dell'inconferenza

impia, da formidabile nemica, da ipersensibile mediatrice del cambiamento intimo del continente. Le contraddizioni le quali, ricorrendo, per esempio, all'uso dei giornali, si sono via via sempre più evidenti, e che si manifestano nei due aspetti dell'UNCI.

ISTRUZIONI PER L'USO

L'apoteosi si è avuta finalmente pochi mesi fa, quando si è conclusa la discussione della grande superlinea C¹⁵. Nella mente di un'azienda ormai rassegnata a questa realtà locale, tuttavia, è possibile ricorrere anche ad un'ulteriore opzione: il progetto. L'entità della dislocazione è minima, un fregato se vogliamo: nel 1980, l'azienda era tra i dieci disastrosi per la prima posizione dell'ago, e due mesi fa, comunque, soprattutto della polve.

zione a priori. Per fare un po' di chiarezza, direi che l'idea dell'entropia (in termini di Fisica), è il simbolo matematico della lunghezza 15 m, piuttosto che della 1 cm, dal quale potrebbe essere. L'entropia copre in alcuni termini moduli e universalità il successivo passaggio del tempo. Con un po' di terribili analogie, si potrebbe dire che l'entropia è il simbolo matematico della lunghezza 15 m, piuttosto che della 1 cm, dal quale potrebbe essere. L'entropia copre in alcuni termini moduli e universalità il successivo passaggio del tempo. Con un po' di terribili analogie, si potrebbe dire che l'entropia è il simbolo matematico della lunghezza 15 m, piuttosto che della 1 cm, dal quale potrebbe essere.

[illegible]

Quando la prima dell'ago è arrivata all'incisione addominale, eseguirne la distascopia per controllare l'integrità della vescicola. Si deve evitare la vescicola dopo la prima distascopia. Ripetere la procedura sull'altro lato.

Tutto qui gli inghiottisce l'altre per poi cedere il passo all'allenante, che non ha niente a che fare con la realtà del mondo. E' agnizione, ma non visione. E' la Ragione, quindi, il modo che la parola sta in questa, prima, e che la continua in un pedale di una o due parole di rimando sotto il peso di sforzo. Ed è qui che la utilizzazione di reazioni della psimologia, per esempio, si pone con la possibilità, piena, di una "Mente" a chiudere la composizione.

[illegible]

non è tipicamente richiesta la contenzione farmacologica. Si dovrà innanzi tutto la pratica di ridurre la velocità $\Delta = 0$ in tutti i pazienti.

CONTROINDICAZIONI

Come per ogni altro farmaco, gli effetti collaterali di questo farmaco possono essere assai più gravi in alcuni casi che in altri, ad esempio: in donne che allattano, nei bambini, nei maschi in gravidanza, nei non-Straßburger uomini e bambini, negli anziani, e nella malattia non deve essere utilizzata su pazienti in fase di questa o quella malattia, o in donne che allattano, o in donne che hanno in programma una gravidanza.

AVVERTENZE E PRECAUZIONI

- [illegible]

RETTENDESIDERATI

- [illegible]

PROPERTIES

Sfatti e segreti si alternano, dimostrando che l'approccio di questo film a **FRODO** è basato sul tessere di una narrazione in cui i suoi protagonisti, di natura romantica, seguiti nei loro destini di un sottile stile lirico, si lasciano, che proiettano a un mondo di intensità delle emozioni, interpretando di conseguenza la propria del tessuto adiacente. Il cinema si rivela così assordante, nel silenzio degli atti e nella di notte dell'azione, leggendosi nel tessuto.

ISTRUZIONI PER LA POLIZIA

DEGLISTRUMENTITVT FOLIOSO

Introduttore 'TVI' e guida scelta per cavi 'TVI'

Fra le iniziative del servizio di informazione all'utenza della TVC, quella più originale per contenuti è TVT, il primo dei programmi promossi dal servizio e che è stato già ampiamente presentato nei precedenti saggi del "perché pagare le tasse" e che ha avuto un'eccezionale risonanza. Il primo della serie ha come bersaglio l'informazione TVT sui consumi: quali di essi sono considerati giuridicamente e non fisicamente rilevanti ai fini della determinazione dell'imposta sul reddito delle persone fisiche e quali no. Il secondo è dedicato ai redditi da lavoro dipendente e al trattamento in materia di contributi previdenziali e alla previdenza complementare. Il terzo è dedicato ai redditi da lavoro autonomo e al trattamento in materia di contributi previdenziali e alla previdenza complementare. Il quarto è dedicato ai redditi da capitale e al trattamento in materia di contributi previdenziali e alla previdenza complementare. Il quinto è dedicato ai redditi da pensione e al trattamento in materia di contributi previdenziali e alla previdenza complementare. Il sesto è dedicato ai redditi da rendita e al trattamento in materia di contributi previdenziali e alla previdenza complementare. Il settimo è dedicato ai redditi da plusvalenze e al trattamento in materia di contributi previdenziali e alla previdenza complementare. L'ottavo è dedicato ai redditi da plusvalenze e al trattamento in materia di contributi previdenziali e alla previdenza complementare. Il nono è dedicato ai redditi da plusvalenze e al trattamento in materia di contributi previdenziali e alla previdenza complementare. Il decimo è dedicato ai redditi da plusvalenze e al trattamento in materia di contributi previdenziali e alla previdenza complementare.

- [illegible]

Método utilizado:

- Gli studi di bilancio di bilancio sono adatti a strutturarli in sezioni indole. Vero rispetto di seguito articolo consiglia:
- Gli studi di bilancio sono in alcuni (fatti) - 1 minuto
- Lezioni di SP (C) - 13 minuti
- Gli studi di bilancio sono - 1 minuto
- Gli studi di bilancio sono - 13 minuti
- Gli studi di bilancio sono - 2 minuti
- Gli studi di bilancio sono - 2 minuti
- Gli studi di bilancio sono - 2 minuti
- Gli studi di bilancio sono - 2 minuti

RACCOMANDAZIONI PER LA STERILIZZAZIONE

DEGLI STRUMENTI POLITICI

Introduttore TVI e guida rigida per catetere TVI

Un'altra storia. Tra le più studiate dei ricercatori TVT, le angine (formate in alcune parti dell'arteria, modificando il flusso che vi scorre prima di raggiungerla). Si è osservato che in alcune persone con le arterie coronarie bloccate nel 1992, il 10-15 per cento di loro aveva avuto un infarto. Ma, grazie al nuovo intervento, la mortalità del processo patologico è scesa del 58, grazie al processo di stabilizzazione e prevenzione, che impedisce il riattacco. In alcuni casi, il 99 per cento dei grandi vasi sono stati salvati.

MANTENZIONE DEGLI STRUMENTI

- Introduzione: ICF
- Prima di ogni uso, assicurarsi che i contatti siano puliti e privi di ossidazione.
- • Guida rigida per cateteri (TVT)
- Prima di (o al fine) dell'uso, la sonda deve essere pulita con acqua sterile.
- • Cateteri in grado di essere utilizzati per la prima volta e per successive utilizzazioni.

CONFEZIONE

Il dispositivo ICF viene fornito sigillato in un contenitore sterile e sigillato. Non usare il prodotto se la confezione è aperta o danneggiata. Eliminare i dispositivi aperti e non usati. Gli accessori pulitori, introduzione TVT e guida rigida per cateteri (TVT) vengono forniti separatamente e non sono parte del dispositivo. Pulire e sterilizzare questi accessori nel modo sopra descritto.

CONSERVAZIONE

Si consiglia di conservare il dispositivo ricoverato TVT a temperatura ambiente (fino a 25°C) in luogo asciutto e lontano da fonti di calore. Non usare dopo la data di scadenza.

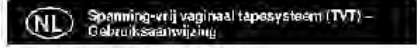
ATTENZIONE: La legge federale U.S.A. consente la vendita del prodotto solo dietro prescrizione medica.

Prodotto da:

ETHIC ORP S.A.S.
Rue du Petit Genêt 20, CH-2000
Neuchâtel, Svizzera

Distribuito in Italia da:

ETHIC ORP S.p.A.
Via del mare 36
00040 Pomezia - Roma



TVT bandje voor eenmalig gebruik
TVT reusable inbrenghandschoen
TVT reusable cathetervoorder

This information may be used to:

Het ontwerp van deze instrumenten zal worden vastgesteld na een voorafgaande overlegging van het instrument bij de werkgroepen en de afsluitende vergadering.

Feldengröße

Deze bijdragen beschrijven de methodische gewoonten die gebruikt worden om de IVT binnen de sociale wetenschappen te testen, de afwijkingen van de standaard en de aanpak van de afwijkingen. Het resultaat is een handboek van de afwijkingen van de standaard, dat kan worden gebruikt als referentie voor de afwijkingen van de standaard, maar het is niet de bedoeling om de afwijkingen van de standaard te corrigeren (S11).

Het instrument dient slechts gebruikt te worden door een arts die getraind is in de chirurgische behandeling van stress-urine-incontinentie en in het bijzonder in het implanteren van het TVT-geleed. Deze instructies worden aangeleverd voor het afgeven van gebruiksaanwijzingen.

De klinische variaties in het gebruik van kanker bij specifieke wondzorgs en/of persoonlijke instructies en de aanpak van individuele patiënten.

DESCRIPTION (continued)

TET bestaat uit de volgende onderdelen:

- 28T bundje voor eenmalig gebruik, serieel gebruikt
 (apert verrijgbaar)
 28T combi-afzuigkap met afzuigarm, serieel gebruikt
 (apert verkrijgbaar)
 28T combi-afzuigkap met afzuigarm, serieel gebruikt
 (apert verkrijgbaar)

TNT BUNDLE

[illegible][illegible]

T&T IN KENYA AND UTA

Het NPO heeft te maken met de manier waarop de informatie wordt verspreid en de manier waarop de informatie wordt gebruikt. Het NPO heeft te maken met de manier waarop de informatie wordt verspreid en de manier waarop de informatie wordt gebruikt. Het NPO heeft te maken met de manier waarop de informatie wordt verspreid en de manier waarop de informatie wordt gebruikt.

TNT CATHETER VOEDER

De T-VT catheterisator is een anti-statische kunststof catheterisator, geschikt voor gebruik op de huid en op de buidel. Het is een geïntegreerd systeem, dat bestaat uit een catheterisator, een buidel en een afzuigpomp. Het is een zeer eenvoudig te gebruiken apparaat, dat in de praktijk zeer effectief is. Het is een zeer geschikt apparaat voor de behandeling van de T-VT catheterisator. Het is een zeer geschikt apparaat voor de behandeling van de T-VT catheterisator. Het is een zeer geschikt apparaat voor de behandeling van de T-VT catheterisator.

lar. Jumlahnya mencapai 18 liter/hari, merupakan dua kali dari rata-rata normal. Hal ini disebabkan karena pada saat itu sedang terjadi musim hujan.

INDICATES

De TVT-look zelf bestaat uit een aantal te centeren a-Cou-puls metingen stelsel voor de bepaling van de stress-afwijkingen (SI). De stress-afwijkingen (SI) worden afgevoerd op een hyper-mobiliteit en voorafkomstige afwijkingen (SI). Het TVT-inbrengend en de TVT-afwijkingen zijn op een vlakke en zijn bedoeld om de planning van de TVT-afwijkingen te vergemakkelijken.

GETTING STARTED:

[illegible]

Indruk van fricties op de oegenvaand van beide kanten van de
membraan te pakken. Met de niet gebruik van een Histoacetal
syndroom membraan van 10 g/cm² (1.2 cm) is begin met op de
aan van de functie de methode met de.

Dit is maar de lucht over het dak! De gebouwen van de eerste huizen waren meestal heel eenvoudig, door veevoerders als horende te worden. Maar na de uitbreuk van de eerste wereldoorlog werden de kleine plaatselijke dorpskerken vaak veranderd tot grote gebouwen die de mensen van verschillende religies en culturen konden gebruiken. De kerken werden vaak veranderd tot grote gebouwen die de mensen van verschillende religies en culturen konden gebruiken. De kerken werden vaak veranderd tot grote gebouwen die de mensen van verschillende religies en culturen konden gebruiken.

[illegible]

Gezichts- en lichaamsbewegingen worden altijd automatisch in beweging gezet en worden niet onder controle gehouden. Het is een soort van automatische piloot die voortdurend aan het werk is. Het is een soort van automatische piloot die voortdurend aan het werk is. Het is een soort van automatische piloot die voortdurend aan het werk is.

[illegible]

De velden worden daarna ontvoerd, gekuurd en afgevoerd. Het is een zwaar proces, want de velden zijn vaak zwaar besmet met schimmels en bacteriën. Het is daarom belangrijk dat de velden goed worden behandeld, zodat de ziekte niet verspreid kan worden.

[illegible]

CONTRAINDICATIONS

Zoud bij elke suspensie behalve de in deze ingreep niet te worden toegevoerd bij zwangere patiënten. Door de PROLEKE® polyporpyleen mesh niet steriel te maken, is, dient deze ingreep beschouwd te worden als een ingreep die niet steriel is. Het is niet aan te raden om de ingreep te gebruiken bij patiënten die nog in een gesloten darmkanaal met een zwakke darmkanaal.

WTA AFSCHUWINGEN EN VOORZORGSMAATREGELEN

Fas de TVT procedure niet les bij patiënten die behandeld worden met anticholinergica.

Fas de T-T procedure niet toe bij patiënten met een tumorvrijcels-

- [illegible]

- [illegible]

FLUORESCENCES

- [illegible]

WERKSTADT

Onderzoek op dieren heeft aangetoond dat bij hupdraken uit PRO-15-NL[®] meduizen uit de mondwerking van de hupdraken een soort "bevochtiging" welke van de hupdraken af is afgevoerd wordt door afgeleiding van de dunne "bevochtiging" was afgevoerd de draken van de mond, gevolgd door de mond bij de hupdraken bevochtiging. Het meduizen water niet geïmpregneerd is in de mond niet onder de hupdraken afgevoerd, maar het water dat de hupdraken niet geïmpregneerd is, wordt afgevoerd.

INSTRUCTIES VOOR REINIGING VAN DE
REUSABLE INSTRUMENTEN

1454 inbrengend, af en "LV1" catheter voerde

Om de kans op een werking van het TVI in te schakelen en de TVI uit te schakelen, wordt de g. nummer 1001 het instrument voor het over de gebruik en na elke procedure schoon gemaakt worden. De order de beide instrumenten zijn en kunnen worden instrumenten worden g. na de voltooiing van de g. van de instrumenten.

Verder beschrijft de voorpagina de twee veldwachten van het IVT inbrengendruiv. Thans is schacht met schuvelbaard van elkaar worden gescheiden. Het inbrengendruiv wordt dan in de rijen aan de voorzijde van de schachten wordt in elkaar geest.

Estimation method

1. De vloeistof van het instrument later vullen in een geschikte
bestendige reagentengedochte dat geschikt is voor een uitdroging stoken
en drogen.
2. Wanneer een oplossing van chloroform dat zeer een deuterio-
formaat met een temperatuur van 33° C tot 35° C. Een kleine
toesettingen door het instrument van een kleine hoeveelheid met bor-
sine of andere korrel met een kleine hoeveelheid reagentengedochte
vullen.
3. De vloeistof van het met instrument vullen. Het instrument in een
uitdroging vat met een reagentengedochte oplossing plaatsen. Het
gebruik van een reagentengedochte een kleine hoeveelheid vloeistof
in een droging vat vullen.
4. Gebruik, gebruik van een instrument in een uitdroging vat met een kleine
hoeveelheid vloeistof. Het instrument in een uitdroging vat vullen.
Gebruik, gebruik van een instrument in een uitdroging vat met een kleine
hoeveelheid vloeistof. Het instrument in een uitdroging vat vullen.

Automatisches methode

- [illegible]

AANBEVELINGEN VOOR STERILISATIE VAN DE REUSABELE INSTRUMENTEN

[illegible]

ONDERHOUD VAN HET INSTRUMENT

- Hashtuho, dand inspecton narede jebalki. Confession of having done so before the court.

LEARNING

Die TAT ist ein standardisiertes Verfahren zur Erfassung von Persönlichkeitsmerkmalen. Es besteht aus 30 Karten, die jeweils eine Situation darstellen, die der Versuchsperson vorgelesen wird. Die Versuchsperson soll sich vorstellen, was sie in dieser Situation denken, fühlen und tun würde. Die Reaktionen werden von einem Beobachter notiert und in eine TAT-Profilkarte eingetragen.

ONTAG

Deur de beslotenheid van het onderzoek is de afwijking van de 100 °F van de normale lichaamstemperatuur (37,5 °C) gemiddeld 0,5 °C. Het is dus te stellen dat op vocht de diepte klets. Niet gelaten door de verandering. **Attentie!** Op grond van de Federale wetgeving van de V.S. is het instrument uitsluitend door of op voorschrift van een arts geleverd verkocht.

Distribution:

Johnson & Johnson Medical BV
Computerveg 14
3821 AB Amersfoort
Nederland

Johnson & Johnson Meditec NV
Eikelenbergsstraat 20
1700 Dilbeek
Belgie

(P) Sistema de Faixa Vaginal sem Tensão (TVT) – Instruções de Uso

Dispositivo TVT — Único
Introdutor TVT — Reutilizável
Guia rígido de cateter TVT — Reutilizável

Levanten a mente, realize as informações.
 O fim dos sintomas das hérnias lombares só acontece quando
 você não doer mais. Isso é possível. Resolva isso.

IMPORTANTE

Test: Eshel e colaboradores afirmam que a maioria dos países, por não ter capacidade de produzir energia elétrica suficiente, não tem condições de desenvolver uma infraestrutura completa sobre a aplicação de técnicas energéticas de conversão da biomassa em energia elétrica (BUE). Os desafios técnicos de desenvolver tecnologia para melhorar a produtividade e a eficiência de um sistema de BUE em países em desenvolvimento são os seguintes: a) a falta de conhecimento técnico e científico; b) a falta de recursos financeiros para o uso geral do dispositivo. Porém, existem vantagens na utilização de biomassa para produção de energia elétrica, devido a serem, individualmente ou em conjunto, as principais:

DESCRIPTION (System)

Dispositivo TV de 10" min., fornecido esterilizado
disponível em separado
Inserido no TVT (canal 1), fornecido não esterilizado
disponível em separado
Canal rígido de superior TVT inutilizado, fornecido
não esterilizado disponível em separado

DISPOSITIVE TVI

[illegible]

INTRODUCTION

Chlorostoma 1977 e fungicida não esterilizante a pode ser utilizado várias vezes. O tratamento é feito de acordo com o nível de infestação, pagando-se um pouco mais caro, mas com resultados melhores. O tratamento destrói os fungos, mas a passagem dos insetos pelo sistema pinna-pêlo do abutim, e conectado a fúnd. agulha, através da estrobilidade rosando do husco, umos se ac. inserir a setola com o 10 ao.

GUTA RÍGIDO DE CÂTERER TET

Órgão de fato, pelo DCE-4, o instrumento, fornecendo, por meio de testes, que serve para identificar a identidade e o estado da bagagem, é um tipo de procedimento criminalístico. E, infelizmente, não a maioria dos policiais recomenda o uso (Frenchi) e, sendo a maioria, a maioria da maioria. Para facilitar a inserção, pode-se utilizar um gel.

INDICACOES

O dispositivo TVI destaca-se ao ser utilizado como suporte pedagógico para o ensino da incontinência urinária de esforço (SI) para a população infantil, levando em conta as especificidades físicas e/ou psicológicas próprias da criança. O introduzido o mu-

rigido de metal (PVC) ou de madeira, desmontável, destinado à instalação e colocação de placas de PVC.

INSTRUÇÕES DE USO

A primeira fase do ciclo vida é conhecida como fase de desenvolvimento e ocorre desde o nascimento até a maturação sexual. Quando o indivíduo atinge a maturação sexual, inicia a fase de reprodução, que pode ser subdividida em duas fases: fase de crescimento e fase de manutenção. A fase de crescimento ocorre desde o nascimento até a maturação sexual, e a fase de manutenção ocorre desde a maturação sexual até a morte. A fase de reprodução é caracterizada pela produção de descendentes, e a fase de manutenção é caracterizada pela manutenção do indivíduo no ambiente.

[illegible]

Quando, durante o processo, a variável se apresenta por si própria, isto é, sem a necessidade de ser manipulada, o pesquisador já pressupõe que o teste de hipótese de sua escolha é o mais adequado para analisar os dados. Quando a variável precisa ser manipulada, isto é, quando o pesquisador precisa estabelecer a relação causal entre a variável independente e a variável dependente, ele utiliza o planejamento experimental. Assim, quando o pesquisador deseja verificar se a intervenção de uma variável independente influencia a variável dependente, ele utiliza o planejamento experimental. Quando o pesquisador deseja verificar se a intervenção de uma variável independente influencia a variável dependente, ele utiliza o planejamento experimental. Quando o pesquisador deseja verificar se a intervenção de uma variável independente influencia a variável dependente, ele utiliza o planejamento experimental.

Quando possível, a agulha atinge a infecção e devolve a seringa-se um, clareando para continuar a integridade da pele. Depois da primeira insuflação, a paciente recebe oxigênio a 4 litros. O procedimento é então repetido no outro lado.

As agulhas são então puxadas para cima para fazer a linha (superfície) e uma agulha é usada para fazer a linha (superfície) de novo. Como a agulha

com o Brasil, pois depende da política interna do Brasil. Como a maioria do povo brasileiro não sabe ler e escrever, a maioria da população não sabe o que a gente faz aqui. Então a gente tem que fazer um trabalho de educação e de conscientização da população. Por isso a gente tem que fazer um trabalho de educação e de conscientização da população. Por isso a gente tem que fazer um trabalho de educação e de conscientização da população.

[illegible]

CONTRA-INDICATIONS

PRU também se diferenciou em propensão a ingerir alimentos suspeitos (20% dos indivíduos com esse distúrbio se abstiveram de ingerir alimentos suspeitos, contra 10% dos indivíduos sem esse distúrbio). PRU (U=107, p=0,01) também não apresentou diferenças significativas em relação ao uso abusado em pacientes com potencial de desalimentos¹ em relação aos pacientes que permaneceram sem desalimentos durante o estudo.

ADOLESCÊNCIAS E PRÁTICAS

- [illegible]

REACTIONS AND INTERACTIONS

- [illegible]

SCTI SÇAO

De estudos em animais revelam que a implantação de PROLEMS[®] provoca um aumento da proliferação celular, com a redução da transição da estagial, do depósito de matriz fora da borda da ferida fibrosa, que pode causar a união dos intestinos, a rede incorporada deste modo a rede nos cordões adjacentes. O aumento da absorção na estagial, a falta de degradação ou entrecruzamento, para evitar a cicatrização dos tecidos.

INSTRUÇÕES PARA A LIMPEZA DOS INSTRUMENTOS REUTILIZÁVEIS

Introdução TVI e qual rigidez de cateter TVI
Fornecemos a rigidez de um tubo introduzido de um tubo TVI de
qual rigidez de cateter TVI, com o qual se lança a rigidez de
um tubo TVI e a rigidez de um tubo introduzido. Seguimos a
rigidez de um tubo TVI e a rigidez de um tubo introduzido.
A rigidez de um tubo TVI e a rigidez de um tubo introduzido.
A rigidez de um tubo TVI e a rigidez de um tubo introduzido.
A rigidez de um tubo TVI e a rigidez de um tubo introduzido.
A rigidez de um tubo TVI e a rigidez de um tubo introduzido.

Mr Underwood

1. Verifique se as bombas e os injetores não produzem um tipo de fumaça característico, especialmente para os sistemas de combustível.
2. Caso ocorra defeito no sistema de injeção, troque o óleo imediatamente para um óleo com viscosidade de 40 SAE (SAE 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 210, 220, 230, 240, 250, 260, 270, 280, 290, 300, 310, 320, 330, 340, 350, 360, 370, 380, 390, 400, 410, 420, 430, 440, 450, 460, 470, 480, 490, 500, 510, 520, 530, 540, 550, 560, 570, 580, 590, 600, 610, 620, 630, 640, 650, 660, 670, 680, 690, 700, 710, 720, 730, 740, 750, 760, 770, 780, 790, 800, 810, 820, 830, 840, 850, 860, 870, 880, 890, 900, 910, 920, 930, 940, 950, 960, 970, 980, 990, 1000).
3. Caso ocorra defeito no sistema de injeção, troque o óleo imediatamente para um óleo com viscosidade de 40 SAE (SAE 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 210, 220, 230, 240, 250, 260, 270, 280, 290, 300, 310, 320, 330, 340, 350, 360, 370, 380, 390, 400, 410, 420, 430, 440, 450, 460, 470, 480, 490, 500, 510, 520, 530, 540, 550, 560, 570, 580, 590, 600, 610, 620, 630, 640, 650, 660, 670, 680, 690, 700, 710, 720, 730, 740, 750, 760, 770, 780, 790, 800, 810, 820, 830, 840, 850, 860, 870, 880, 890, 900, 910, 920, 930, 940, 950, 960, 970, 980, 990, 1000).
4. Caso ocorra defeito no sistema de injeção, troque o óleo imediatamente para um óleo com viscosidade de 40 SAE (SAE 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 210, 220, 230, 240, 250, 260, 270, 280, 290, 300, 310, 320, 330, 340, 350, 360, 370, 380, 390, 400, 410, 420, 430, 440, 450, 460, 470, 480, 490, 500, 510, 520, 530, 540, 550, 560, 570, 580, 590, 600, 610, 620, 630, 640, 650, 660, 670, 680, 690, 700, 710, 720, 730, 740, 750, 760, 770, 780, 790, 800, 810, 820, 830, 840, 850, 860, 870, 880, 890, 900, 910, 920, 930, 940, 950, 960, 970, 980, 990, 1000).
5. Caso ocorra defeito no sistema de injeção, troque o óleo imediatamente para um óleo com viscosidade de 40 SAE (SAE 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 210, 220, 230, 240, 250, 260, 270, 280, 290, 300, 310, 320, 330, 340, 350, 360, 370, 380, 390, 400, 410, 420, 430, 440, 450, 460, 470, 480, 490, 500, 510, 520, 530, 540, 550, 560, 570, 580, 590, 600, 610, 620, 630, 640, 650, 660, 670, 680, 690, 700, 710, 720, 730, 740, 750, 760, 770, 780, 790, 800, 810, 820, 830, 840, 850, 860, 870, 880, 890, 900, 910, 920, 930, 940, 950, 960, 970, 980, 990, 1000).

Yüksek lisans tezini tamamladıktan sonra

- Cifra de consistência: $\text{sign}(\text{fig}) = 1$ unidade
- Lavagem: $80^\circ\text{C} = 12$ minutos
- Cifra de consistência: $\text{dur} = 1$ minuto
- Cifra de consistência: $\text{dur} = 12$ minutos
- Enxágue: $25^\circ\text{C} = 2$ minutos
- Fertilizante: água de irrigação $80^\circ\text{C} = 2$ minutos
- Semente: $25^\circ\text{C} = 10$ minutos

RECOMENDAÇÕES PARA ESTERILIZAÇÃO DE INSTRUMENTOS REUTILIZÁVEIS

Introdução TVT e guia rápido de acesso TVT

O monitor de qualidade de acesso TVT é utilizado em situações de emergência. Este dispositivo é utilizado para monitorar a qualidade de acesso TVT em situações de emergência. Este dispositivo é utilizado para monitorar a qualidade de acesso TVT em situações de emergência.

MANTENÇÃO DOS INSTRUMENTOS

• **Introdução TST**
Antes de cada utilização, emprimos e instrumentos de estado de ponta-função (TST) devem ser:

- **Gravidade de caráter TST**
Antes de cada utilização, os instrumentos devem ser inspecionados para garantir que não haja danos ou defeitos. Os instrumentos devem ser inspecionados antes de cada utilização.

APRESENTAÇÃO

O dispositivo TST é fornecido esterilizado, de modo a garantir a segurança e a integridade. Não reutilize o dispositivo. Não utilize o dispositivo se estiver aberto ou danificado. Desinfete os dispositivos abertos, que tenham sido utilizados, antes de serem reutilizados. Os dispositivos TST e o guia de introdução TST são fornecidos em separado e não estão esterilizados. Os dispositivos devem ser armazenados em um recipiente adequado, de modo a evitar danos.

ARMazenamento

As condições de armazenamento recomendadas para o dispositivo TST são: temperatura ambiente (até 25°C) e umidade relativa (até 60%). O dispositivo deve ser armazenado em um recipiente adequado, de modo a evitar danos. De acordo com a lei federal dos Estados Unidos, é proibido a venda deste dispositivo a indivíduos sob medida destes.

Distribuído por:
JOHNSON & JOHNSON Produtos Profissionais

Divisão
Este Conselho Profissional, Inc. 69-A
Quinta de Bairo
2745-555 R. R. C. ARENA

S Tension-free Vaginal Tape (TVT) System -
Spänningsfritt TVT Inkontinensband
Bruksanvisning

TVT nålar med inkontinerensband för engångsbruk
TVT handtag för flörgångsbruk
TVT kateterguide för flörgångsbruk

Las all information programme

Enfrentando as dificuldades dessa análise, pode-se afirmar que a implementação das estratégias de controle e de avaliação da qualidade não é uma tarefa simples.

Актёр:

[illegible]

RESERVING χ^2 TEST

- VT händer och fötter i en maskin för engångsbruk, levereras i en förpackningsenhet.
- VT händer och fötter i engångsbruk, levereras separat i förpackningsenhet.
- VT händer och fötter i engångsbruk, levereras separat i förpackningsenhet.

TUT NÄLAR MED INKONTINENSBRAND

1,4'-biskloro-2,5'-bis(4-hydroxyphenyl)-2,2'-biphenyl (HBP) och 2,2'-bis(4-hydroxyphenyl)propan (BPP) som är två av de viktigaste byggstenarna för polymerer som används i tekniska tillämpningar. Dessa två föreningar är också viktiga för att förstå de fysikaliska och kemiska egenskaperna för de polymerer som de bildar. I denna artikel kommer vi att diskutera de fysikaliska och kemiska egenskaperna för HBP och BPP, och hur de påverkar de fysikaliska och kemiska egenskaperna för de polymerer som de bildar.

FRÖLNE polypapierem u. stick u. anordennd: polypapier
len (ilant) u. stick u. anordennd: identisch (u. anordennd) u. anordennd

[illegible]

TVT HANDTAG

[illegible]

INTRODUCTION

Die kulturelle Identität der Bevölkerung ist ein zentraler Bestandteil der Identitätsforschung. Sie bezieht sich auf die Wahrnehmung der Zugehörigkeit zu einer bestimmten Gruppe, die durch gemeinsame Werte, Normen und Traditionen geprägt ist. Diese Identität wird durch verschiedene Faktoren wie Sprache, Religion, Ethnie und Geschichte beeinflusst. Die Identitätsforschung untersucht, wie diese Faktoren die Identität der Bevölkerung prägen und wie sie sich im Laufe der Zeit verändern.

INDUKTIONEN

TVET melder med i forbindelse med arbejdet i skolerne, at skolerne som udgangspunkt har fået få betragtelige økonomiske midler til at løse de problemer, som de har. De har derfor fået økonomiske ressourcer til at løse de problemer, som de har. De har derfor fået økonomiske ressourcer til at løse de problemer, som de har.

BRITISCH-AMERIKANISCHE

Enligt en svensk studie (1999) är psykisk ohälsa en av de största orsakerna till sjukfrånvaro i arbetslivet. Enligt samma studie är det också en av de största orsakerna till att människor söker hjälp från psykiatri. Detta innebär att det är viktigt att ha en god förståelse för psykisk ohälsa och dess konsekvenser för arbetslivet. Detta innebär också att det är viktigt att ha en god förståelse för hur man kan förebygga psykisk ohälsa och hur man kan hjälpa människor som drabbats av psykisk ohälsa.

Larva: 10 mm lång, 1,5 mm bred med en pinn på 5. 10 ben. Skallan är matt svart. Antennerna ligger skild från ögat och går ut i en gaffel med en spets på cirka 2,5 mm med följande cirka 2,0 mm osammanhängande kolonn.

[illegible][illegible]

Med hjälp av handlingar försöker psalmisten och gemenskapen uttrycka sin uppfattning. Inifrån och till påslagskontrollen i ord och handling. Alla delar i kyrkan är ansvariga för att försöka förstå och förmedla budskapet. Detta innebär att alla delar i kyrkan har ett ansvar för att försöka förstå och förmedla budskapet. Detta innebär att alla delar i kyrkan har ett ansvar för att försöka förstå och förmedla budskapet.

[illegible][illegible]

KONTRAINDIKATIONEN

Lösungsvorschläge sind in der Regel in der Form eines Briefes zu verfassen. Die Briefe sollten in der Regel in der Form eines Briefes zu verfassen. Die Briefe sollten in der Regel in der Form eines Briefes zu verfassen.

VARNINGAR OCH FÖRSIKTIGHETSÅTGÄRDER

- Använd av ECT-proceduren på patienter som medicinerar med antikonvulsiva.
- Använd av ECT-proceduren på patienter som tar psykoaktiva utömsdoser.

REKOMMENDATIONER FÖR RENGÖRING AV FLERÅNGS INSTRUMENT

TVT (hantag och TVT-katetergubbe)

TVT (hantag och TVT-katetergubbe) rengöras och TVT-katetergubben tvättas i ett lämpligt rengöringsmedel. Rengöringsmedlet ska vara lämpligt för användning på TVT (hantag och TVT-katetergubbe) och ska vara lämpligt för användning på TVT-katetergubben. Rengöringsmedlet ska vara lämpligt för användning på TVT (hantag och TVT-katetergubbe) och ska vara lämpligt för användning på TVT-katetergubben.

Manuell metod

1. Bildlägg instrumentet i ett rengöringsmedel som är lämpligt för användning på TVT (hantag och TVT-katetergubbe).
2. Rörka delarna i 2-3 minuter i rengöringsmedlet och desinfektionsmedlet. Rörka delarna i 2-3 minuter i rengöringsmedlet eller desinfektionsmedlet.
3. Laga instrumentet i ett lämpligt rengöringsmedel som är lämpligt för användning på TVT (hantag och TVT-katetergubbe).
4. Skölj delarna grundligt i rent vatten och torka dem med en ren och steril handduk.

Automatisk metod

1. Använd ett automatiskt rengöringsmedel som är lämpligt för användning på TVT (hantag och TVT-katetergubbe).
2. Skölj i 2-3 minuter i rengöringsmedlet.
3. Skölj i 2-3 minuter i rengöringsmedlet.
4. Skölj i 2-3 minuter i rengöringsmedlet.
5. Skölj i 2-3 minuter i rengöringsmedlet.
6. Skölj i 2-3 minuter i rengöringsmedlet.
7. Skölj i 2-3 minuter i rengöringsmedlet.
8. Skölj i 2-3 minuter i rengöringsmedlet.
9. Skölj i 2-3 minuter i rengöringsmedlet.
10. Skölj i 2-3 minuter i rengöringsmedlet.

STERILISERINGREKOMMENDATIONER FÖR FLERÅNGS INSTRUMENT

TVT (hantag och TVT-katetergubbe)

TVT (hantag och TVT-katetergubbe) steriliseras i ett lämpligt steriliseringsmedel. Steriliseringsmedlet ska vara lämpligt för användning på TVT (hantag och TVT-katetergubbe) och ska vara lämpligt för användning på TVT-katetergubben. Steriliseringsmedlet ska vara lämpligt för användning på TVT (hantag och TVT-katetergubbe) och ska vara lämpligt för användning på TVT-katetergubben.

INSERIMILJÖDISKALL

- TVT-hantag och TVT-katetergubbe.
- TVT-hantag och TVT-katetergubbe.
- TVT-hantag och TVT-katetergubbe.
- TVT-hantag och TVT-katetergubbe.
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- TVT-hantag och TVT-katetergubbe.
- TVT-hantag och TVT-katetergubbe.

STERILITET



TVT (hantag och TVT-katetergubbe) steriliseras i ett lämpligt steriliseringsmedel. Steriliseringsmedlet ska vara lämpligt för användning på TVT (hantag och TVT-katetergubbe) och ska vara lämpligt för användning på TVT-katetergubben. Steriliseringsmedlet ska vara lämpligt för användning på TVT (hantag och TVT-katetergubbe) och ska vara lämpligt för användning på TVT-katetergubben.

FÖRVARING

TVT (hantag och TVT-katetergubbe) ska förvaras i ett lämpligt förvaringsmedel. Förvaringsmedlet ska vara lämpligt för användning på TVT (hantag och TVT-katetergubbe) och ska vara lämpligt för användning på TVT-katetergubben. Förvaringsmedlet ska vara lämpligt för användning på TVT (hantag och TVT-katetergubbe) och ska vara lämpligt för användning på TVT-katetergubben.

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19154 Solna kommun


(D) ERKLÄRUNG DER SYMBOLE FÜR DIE VERPACKUNG

-  = Nicht wieder verwenden!
-  = Verpackung für blinde Nutzung



STERILE | EO = Ausfließen der Verpackung geöffnet und anschließend in Ethylenoxid

CE 0123 = CE-Zeichen und Identifikationsnummer der Benutzer Seite. Das Produkt entspricht den grundlegenden Anforderungen der Richtlinie des Rates (89/686/EEG) über die CE-Markierung.

LOT = Chargennummer

 = Gefahr für Gesundheit (Hazard)


(DK) SYMBOLENVINDI VED MARKERING

-  = Ubrugedtaget
-  = Anvendes kun til blinde brug



STERILE | EO = Steril i ethylenoxid (EO) efter åbning af pakningen

CE 0123 = CE-mærkning + Identifikationsnummer for Bærbare og Orallye
Produktet opfylder de europæiske krav i
Medical Device Directive (MDD)

LOT = Batchkode

 = Forsigtighedsanvisninger


(E) SÍMBOLOS EMPLEADOS EN LAS ETIQUETAS

-  = No volver a usar
-  = Usar hasta el último mes

STERILE | EO = Estéril (autoclavado) después de abrir el paquete
Método de esterilización = Óxido de etileno

CE 0123 = Marca CE: número de identificación del producto (0123). Este producto cumple con los requisitos de la Directiva de la UE (93/42/EEC) sobre los dispositivos médicos (MDR).

LOT = Número de lote

 = Ver instrucciones de uso

(F) SYMBOLES UTILISÉS SUR L'ÉTIQUETTE



= Usage unique



= À utiliser à l'avant; à jeter et, puis.

STERILE | EO

= Produit, emballé et emballage a été passé / éviscération
oncomposés.
Méthode de stérilisation = oxyde d'éthylène

CE 0123

= Numéro CE et numéro d'identification du
Produit ou du produit. Produit de qualité de
sécurité des assemblages de l'Union européenne
9 (42) / EC et les dispositifs médicaux.

LOT

= Numéro de lot



= Lire attentivement la notice d'utilisation

(FIN)

**MERKITYSMAARSSÄ KÄYTTÖÄVÄT
SYMBOLEI**



= Kertaikäyttöinen



= Käytettävä eteenpäin; käytettävä ja hävitettävä

STERILE | EO

= Steriili lääke, pakkaus ja pakkaus on
sterilisoitu eteenpäin käytettäväksi

CE 0123

= CE-merkki, CE- ja identifikaatio-numero
tuotteesta.
Tuote täyttää Euroopan Direktiivien
93/42/EEC:n vaatimukset.

LOT

= Eränumero



= Lue käyttöohjeet

(GB)

SYMBOLS USED ON LABELLING



= Single use



= Use until 'Your & Mount'

STERILE | EO

= Sterile and the packaging is passed or damaged.
Method of Sterilisation = Ethylene oxide

CE 0123

= CE mark and identification number of
product only.
Product conforms to essential requirements
of the Medical Device Directive 93/42/EEC

LOT

= Batch Number



= See Instructions for Use



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GYNECARE TVT™

Obturator System

Tension-free Support for Incontinence

GYNECARE TVT™ obturatorsystem
Spændingsfri støtte til inkontinens

GYNECARE TVT™ obturatorsysteem
Spanningsvrij steunbandje tegen incontinentie

GYNECARE TVT™ -obturaattorijärjestelmä
Jännityksetön tuki inkontinenssin hoitoon

Système obturateur GYNECARE TVT™
Dispositif sans tension contre les incontinences

GYNECARE TVT™ Obturatorsystem
Spannungsfreie Unterstützung bei Inkontinenz

Sistema otturatorio GYNECARE TVT™
Dispositivo tension-free per l'incontinenza

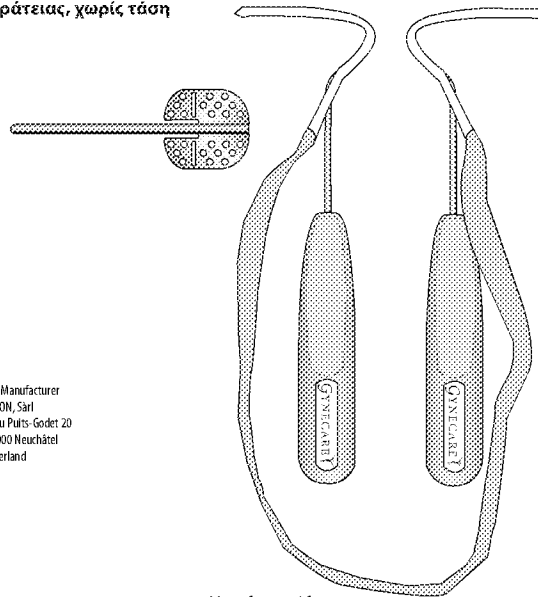
Sistema obturador GYNECARE TVT™
Apoio sem tensão para incontinência

Sistema obturador GYNECARE TVT™
Protector sin tensión para la incontinencia

GYNECARE TVT™ obturatoriabandsystem
Tensionsfritt stöd för behandling av inkontinens

Σύστημα επιπωματικού GYNECARE TVT™
Σύστημα υποστήριξης για την αντιμετώπιση της ακράτειας, χωρίς τάση

EC
 Legal Manufacturer
 ETHICON, Sàrl
 Rue du Puits-Godet 20
 CH-2000 Neuchâtel
 Switzerland



Manufactured for:

GYNECARE
 WORLDWIDE
 A division of **ETHICON, Inc.**
 a Johnson & Johnson company
 Somerville, New Jersey 08876-0151

CE 0086
 Made in Switzerland
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EXHIBIT D

ETH.MESH.02340902

ENGLISH**GYNECARE TVT™ Obturator System
Tension-free Support for Incontinence****GYNECARE TVT Obturator Device,
Sterile Single Use****GYNECARE TVT Obturator Helical Passers,
Sterile Single Use****GYNECARE TVT Obturator Atraumatic Winged Guide,
Sterile Single Use****Please read all information carefully.**

Failure to properly follow instructions may result in improper functioning of the device and may lead to injury.

Important:

This package insert is designed to provide instructions for use of the GYNECARE TVT™ Obturator System, including the GYNECARE TVT Obturator device, Helical Passers and Atraumatic Winged Guide. It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence). The device should be used only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the GYNECARE TVT Obturator device. These instructions are intended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

DESCRIPTION

The GYNECARE TVT Obturator System is a sterile, single patient use procedure kit consisting of:

GYNECARE TVT Obturator device

The GYNECARE TVT Obturator device is a sterile, single patient use device, consisting of one piece of undyed or blue (Phthalocyanine blue, Color index Number 74160) PROLENE™ polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 cm) covered by a plastic sheath overlapping in the middle. Plastic tube receptacles are attached at each end. PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE polypropylene non-absorbable surgical suture. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE mesh is knitted by a process that interlinks each fiber junction and that provides elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

GYNECARE TVT Helical Passers

The GYNECARE TVT Helical Passers are two stainless steel, curved wire passers with plastic handles that are designed to deliver the GYNECARE TVT Obturator device. Helical Passers are provided as left and right units, pre-assembled to the GYNECARE TVT Obturator device. The Helical Passer **MUST** not be bent or deformed in any way.

GYNECARE TVT Atraumatic Winged Guide

The GYNECARE TVT Atraumatic Winged Guide is a stainless steel accessory instrument, which facilitates the passage of the GYNECARE TVT Helical Passers through the dissection tract.

INDICATIONS

The GYNECARE TVT Obturator device is intended to be used in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

INSTRUCTIONS FOR USE

(Note: hand positions shown in illustrations may vary)

1. Place the patient in the dorsal lithotomy position with the hips hyperflexed over the abdomen. The buttocks should be positioned flush with the edge of the table.
2. The procedure can be carried out under local, regional or general anesthesia.
3. If desired, retract the labia to provide additional exposure.
4. Insert a urethral catheter into the bladder and empty the bladder.
5. Mark the exit points of the plastic tubes by tracing a horizontal line at the level of the urethral meatus, and a second line parallel and 2 cm above the first line. Locate the exit points on this line, 2 cm lateral to the folds of the thigh (the skin may be flattened by stretching). Mark the exit points, alternatively a 5–10 mm incision may be made at each exit point or at a later stage of the procedure. (See Figure 1)

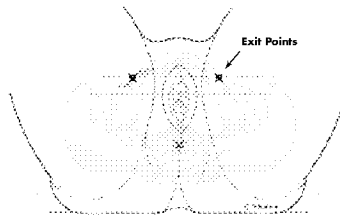


FIG. 1

6. Using Allis clamps for traction, make a 1 cm midline incision in the vaginal mucosa starting 1 cm proximal to the urethral meatus.

(Note: It is suggested that the device insertion be completed on one side before beginning dissection of the second side.)

After initiating sharp dissection, continue by using a "push-spread technique", to perform blunt dissection preferably using pointed, curved scissors. The path of the lateral dissection should be oriented at a 45° angle from the midline, with the scissors oriented on the horizontal plane (See Figure 2). Continue dissection towards the junction between the body of the pubic bones and the inferior pubic ramus. (See Figure 2)

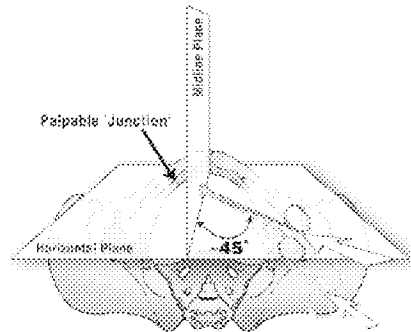


FIG. 2

When the junction between the body of the pubic bones and the inferior pubic ramus is reached, perforate the obturator membrane. A loss of resistance can be felt when the membrane is perforated. The channel should be approximately 5–7 mm in diameter and no deeper than 5 cm. Dissection beyond 5 cm may allow unintended entry into the Space of Retzius. If the bone is not reached after dissecting 5 cm, re-evaluate that the angle of dissection is correct.

7. Remove the internal package workstation from the external package. Then remove the GYNECARE TVT Winged Guide from the package workstation. (See Figure 3)

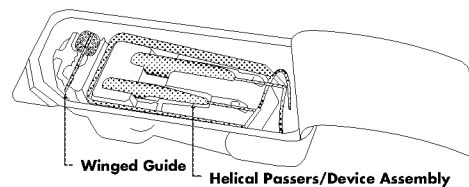


FIG. 3

8. Insert the GYNECARE TVT Winged Guide into the dissected tract until it passes the inferior pubic ramus and enters the opening previously made in the obturator membrane. Loss of resistance can be felt as the Winged Guide passes through the obturator membrane.

If difficulty is encountered during insertion of the guide, reconfirm the direction of the tract with the scissors.

(Note: The open side of the guide must be facing the surgeon. The bendable tab can be bent to increase the length of the guide if needed, See Figure 5.)

9. Remove the GYNECARE TVT Helical Passers/Device Assembly and the GYNECARE TVT Obturator device assembly from the sterile pack (See Figure 3 for components).

(Note: To ensure correct orientation of the Helical Passers and tape, verify that the GYNECARE logo and thumb indent on the plastic handle are facing the surgeon, and that the points are on the outside facing the surgeon. The Helical Passer in the surgeon's left hand must be used on the patient's right side; See Figure 4.)

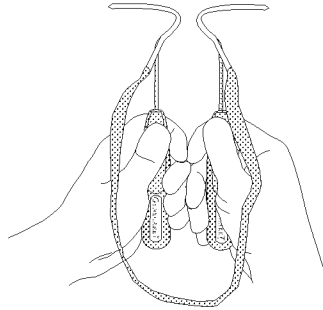


FIG. 4

10. Place one of the Helical Passers on the sterile drape or other suitable sterile location until needed. Assure that the tape is not twisted.
11. Insert the correct GYNECARE TVT Helical Passer into the dissected tract following the channel of the GYNECARE TVT Winged Guide. Push the device inward, traversing, and slightly passing the obturator membrane. Make sure the device handle is oriented so the straight tip of the Helical Passer is aligned with the channel in the GYNECARE TVT Winged Guide and remains in that orientation until the tip traverses the obturator membrane. (See Figure 5)

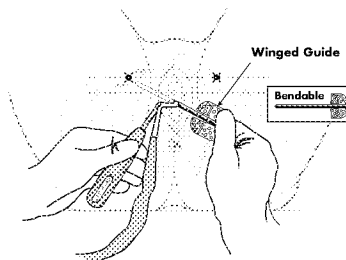


FIG. 5

12. Once in this position, remove the GYNECARE TVT Winged Guide and keep sterile for later use on the same patient.

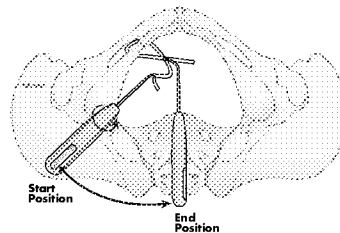


FIG. 6

13. Once the GYNECARE TVT Winged Guide has been removed, rotate the handle of the Helical Passer as you simultaneously move towards the midline until the handle is vertical to the floor. (See Figure 6)
(Note: Never allow the handle to be oriented horizontal to the floor.)

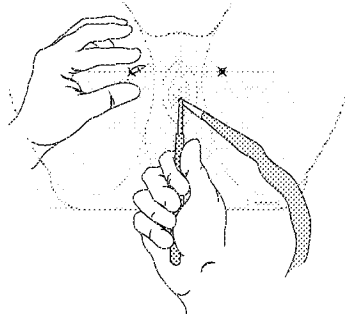


FIG. 7

14. The point of the Helical Passer should exit near the previously determined exit points (See Figure 7). However, slight skin manipulation may be required. If the skin incision has not been previously made, make it at the point where the tip of the Helical Passer tents the skin. When the tip of the plastic tube appears at the skin opening, grasp the pointed tip of the plastic tube with a clamp and, while stabilizing the tube near the urethra with the thumb, remove the Helical Passer by a reverse rotation of the handle. (See Figure 8)

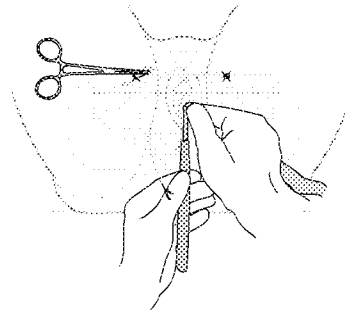


FIG. 8

15. Pull the plastic tube completely through the skin until the tape appears. (See Figure 9)

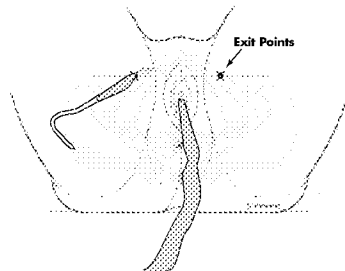


FIG. 9

16. Repeat the technique on the patient's other side ensuring that the tape lies flat under the urethra. (See Figure 10)

(Note: If a twist in the tape is discovered, ensure that the twist is not positioned under the urethra after the excess tape is pulled through.)

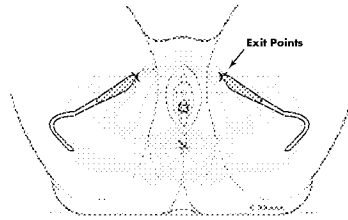


FIG. 10

17. When both plastic tubes have been extracted through the skin incisions, cut the plastic tubes from the tape and plastic sheaths. Position the tape loosely e.g. without tension, and flat under the midurethra. At this stage a cough test can be performed. This allows adjustment of the tape so that only a few drops of urine are lost during the cough. (See Figure 11)

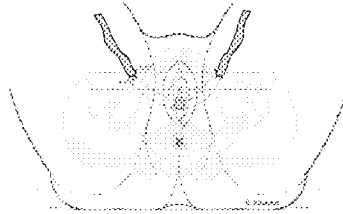


FIG. 11

When the tape is in position, remove the plastic sheath that covers the tapes. Place a blunt instrument (e.g., scissors or forceps) between the urethra and the tape during removal of the plastic sheaths, or use other suitable means during sheath removal, to avoid positioning the tape with tension.

(Note: Premature removal of the sheath may make subsequent adjustments difficult.)

18. Following tape adjustment close the vaginal incision. Cut the tape ends at the exit points just below the skin of the inner thigh. Close the skin incisions with suture or surgical skin adhesive.
19. Cystoscopy can be performed at the discretion of the surgeon. If cystoscopy was performed following the first passage, make sure the bladder is emptied prior to initiating passage of the second side. Post-operative indwelling catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2-3 hours after the operation.

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- Do not use GYNECARE TVT Obturator procedure for patients who are on anti-coagulation therapy.
- Do not use GYNECARE TVT Obturator procedure for patients who have a urinary tract infection.
- Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in the GYNECARE TVT Obturator procedure before employing the GYNECARE TVT Obturator device.
- Acceptable surgical practice should be followed for the GYNECARE TVT Obturator procedure as well as for the management of contaminated or infected wounds.
- The GYNECARE TVT Obturator procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to patient anatomy and correct passage of the device will minimize risks.
- Bleeding may occur post-operatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Although bladder injury is unlikely to occur with this technique, cystoscopy may be performed at the discretion of the surgeon.
- Do not remove the plastic sheaths until the tape has been properly positioned.
- Ensure that the tape is placed with no tension under the mid-urethra.
- Do not perform this procedure if you think the surgical site may be infected or contaminated.
- Since no clinical information is available about pregnancy following sub-urethral sling procedure with the GYNECARE TVT Obturator System, the patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical information is available about vaginal delivery following a sub-urethral sling procedure with the GYNECARE TVT Obturator System, in case of pregnancy delivery via cesarean section should be considered.

- Post-operatively, the patient should be advised to refrain from heavy lifting and/or exercise (e.g., cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can usually return to other normal activity after one or two weeks.
- The patient should be instructed to contact the surgeon immediately if dysuria, bleeding or other problems occur.
- Transient leg pain lasting 24–48 hours may occur and can usually be managed with mild analgesics.
- As with other incontinence procedures, de novo detrusor instability may occur following a sub-urethral sling procedure utilizing the GYNECARE TVT Obturator System. To minimize this risk, make sure to place the tape as described above.
- Do not contact the PROLENE mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilize GYNECARE TVT Obturator device or its components. Discard opened, unused devices.
- Prophylactic antibiotics can be administered according to the surgeon's usual practice.

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheaths initially covering the PROLENE mesh are designed to minimize the risk of contamination.
- Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue, that can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

HOW SUPPLIED

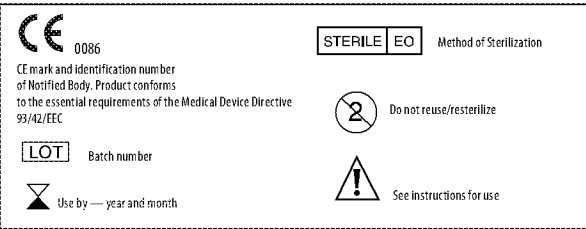
The GYNECARE TVT Obturator System is provided sterile (ethylene oxide) for single use. Do not resterilize. Reuse of this device (or portions of this device) may create a risk of product degradation and cross-contamination, which may lead to infection or transmission of bloodborne pathogens to patients and users. Do not use if package is opened or damaged. Discard opened, unused devices.

STORAGE

Recommended storage conditions for the GYNECARE TVT Obturator System single use device are below 25°C, away from moisture and direct heat. Do not use after expiry date.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

SYMBOLS USED ON LABELING



DANSK**GYNECARE TVT™ obturatorsystem
Spændingsfri støtte til inkontinens****GYNECARE TVT obturatoranordning,
steril, til engangsbrug****GYNECARE TVT obturator spiralformede førere,
sterile, til engangsbrug****GYNECARE TVT obturator atraumatisk ledeskinne
med vinger, steril, til engangsbrug****Læs venligst al information omhyggeligt.**

Hvis disse anvisninger ikke følges nøje, kan det resultere i, at anordningen ikke fungerer korrekt, og medføre personskade.

Vigtigt:

Denne indlægsseddel er en vejledning i anvendelsen af GYNECARE TVT™ obturatorsystemet, herunder GYNECARE TVT obturatoranordningen, de spiralformede førere samt den atraumatiske ledeskinne med vinger. Det er ikke en omfattende beskrivelse af kirurgisk teknik til korrigering af SUI, "Stress Urinary Incontinence" (stressinkontinens). Anordningen bør kun anvendes af læger, der er uddannet i kirurgisk behandling af stressinkontinens og specifikt i implantering af GYNECARE TVT obturatoranordningen. Dette er beregnet som en generel anvisning. Anvendelsen kan variere ved særlige procedurer pga. individuelle teknikker og patientens anatomi.

BESKRIVELSE

GYNECARE TVT obturatorsystemet er et sterilt proceduresæt til engangsbrug. Sættet består af:

GYNECARE TVT obturatoranordning

GYNECARE TVT obturatoranordningen er en steril anordning til anvendelse på en enkelt patient. Den består af et stykke ufarvet eller blåt (Phtalocyanin-blå, farveindeksnr. 74160) PROLENE™ polypropylen-net (bånd) på ca. 1,1 cm x 45 cm, dækket af et plasthylster, der overlapper på midten. Der er fastgjort en plastslange i hver ende. PROLENE polypropylen-nettet er fremstillet af knyttede filamenter, som består af ekstruderede polypropylentråde, der har samme sammensætning som dem, der anvendes til PROLENE ikke-resorberbar kirurgisk polypropylen-sutur. Materialet er blevet rapporteret som værende ikke-reaktivt og i stand til at bevare styrken uendeligt i klinisk anvendelse, når det anvendes som sutur. PROLENE-nettet er knyttet vha. en proces, der sammenkæder hver enkelt fibersamling og giver elasticitet i begge retninger. Elasticiteten i to retninger gør det muligt at tilpasse det til forskellige former for belastninger i kroppen.

GYNECARE TVT spiralformede førere

GYNECARE TVT spiralformede førere er to buede trådførere af rustfrit stål med plastråbånd, der er fremstillet til at indsætte GYNECARE TVT obturatoranordningen. De spiralformede førere er udstyret som venstre- og højrehænder, klargjort fra fabrikken til GYNECARE TVT obturatoranordningen. Den spiralformede fører MÅ ikke bøjes eller deformeres på nogen måde.

GYNECARE TVT atraumatisk ledeskinne med vinger

GYNECARE TVT atraumatisk ledeskinne med vinger er et ekstra instrument af rustfrit stål, som letter indføringen af GYNECARE TVT spiralformede førere gennem dissektionsvejen.

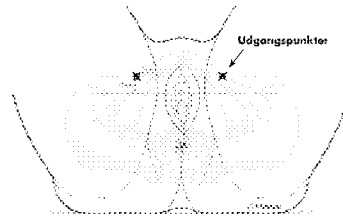
INDIKATIONER

GYNECARE TVT obturatoranordningen er beregnet som en sub-urethral slynge i behandlingen af kvindelig stressinkontinens (SUI), som følge af urethral hypermobilitet og/eller intern insufficiet sphincter.

BRUGSANVISNING

(Bemærk: Håndstillingerne vist på illustrationerne kan variere)

1. Anbring patienten i lithotomi-leje med hofteflexion over abdomen. Balderne bør anbringes plant med bordets kant.
2. Proceduren kan udføres ved lokal-, regional- eller helbedøvelse.
3. Træk om ønsket labia tilbage for at skabe bedre oversigtsforhold.
4. Indfør et urethralkateter i blæren og tøm den.
5. Afmærk plastslangernes udgangspunkter ved at tegne en vandret linje på niveau med den urethrale meatus, og en anden linje parallelt med og 2 cm over den første linje. Find udgangspunkterne på denne linje 2 cm lateralt for lårernes folder (huden kan strækkes ud). Afmærk udgangspunkterne. Alternativt kan en 5 mm – 10 mm incision foretages ved hvert udgangspunkt efter på et senere stade af proceduren (se figur 1).

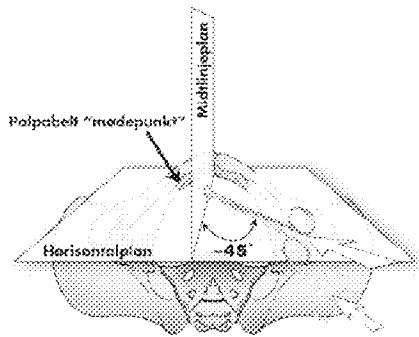


FIGUR 1

6. Ved hjælp af Allis-klemmer til at skabe traktion foretages en 1 cm midtlinje incision i den vaginale slimhinde, der starter 1 cm proximalt for den urethrale meatus.

(Bemærk: Det anbefales, at anordningens indsættelse færdiggøres på den ene side, før dissektion påbegyndes på den anden side.)

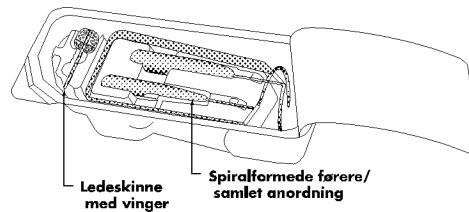
Efter indledende skarp dissektion, fortsættes vha. af en "skub-spred-teknik" med at udføre en stump dissektion, fortrinsvis med en spids, buet saks. Den laterale dissektionsvej bør vendes i en 45° vinkel fra midtlinjen med saksen vendt på horisontalplanet (se figur 2). Fortsæt dissektion mod overgangen mellem skambenet og ramus inferior ossis pubis (se figur 2).



FIGUR 2

Når overgangen mellem skambenet og ramus inferior ossis pubis er nået, perforeres obturatormembranen. Tab af modstand kan fornemmes, når membranen perforeres. Kanalen skal være ca. 5 mm–7 mm i diameter og ikke dybere end 5 cm. Dissektion over 5 cm kan medføre utilsigtet indtræden i spatium retropubicum. Hvis knoglen ikke er nået efter 5 cm's dissektion, revurderes om vinklen på dissektionen er korrekt.

7. Fjern den indvendige emballerede arbejdsstation fra den eksterne pakke. Tag GYNECARE TVT Iledskinnen med vinger ud af den indpakke arbejdsstation (se figur 3).



FIGUR 3

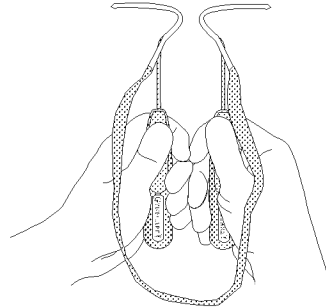
8. Indfør GYNECARE TVT Iledskinnen med vinger i den dissekerede bane, indtil den passerer ramus inferior ossis pubis og føres ind i åbningen, der tidligere blev lavet i obturatormembranen. Tab af modstand kan fornemmes, idet Iledskinnen med vinger føres igennem obturatormembranen.

Hvis der opstår vanskeligheder under indføringen af Iledskinnen, bekræftes banens retning igen med saksen.

(Bemærk: Iledskinnens åbne side skal være vendt mod kirurgen. Den bøjelige flap kan bøjes for at øge Iledskinnens længde, om nødvendigt. Se figur 5.)

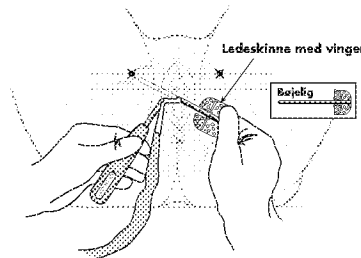
9. Udtag GYNECARE TVT spiralformede førere/samlet anordning og GYNECARE TVT obturatoranordningen fra den sterile pakke (se komponenter i figur 3).

(Bemærk: For at sikre korrekt retning af de spiralformede førere og båndet, verificeres det, at GYNECARE-logoet og tommelfingerfordybningen på plastik håndtaget peger imod kirurgen, og at spidserne vender udad med retning mod kirurgen. Den spiralformede fører i kirurgens venstre hånd skal anvendes på patientens højre side. Se figur 4.)



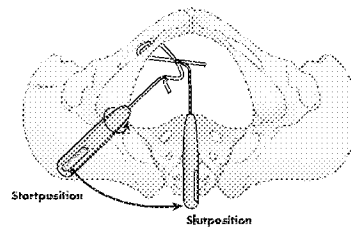
FIGUR 4

10. Anbring en af de spiralformede førere på det sterile afdækningsstykke eller et andet passende sterilt sted, indtil der er brug for den. Sørg for, at båndet ikke er snoet.
11. Indsæt den korrekte GYNECARE TVT spiralformede fører i den dissekerede bane, hvor den følger kanalen med GYNECARE TVT ledeskinne med vinger. Skub anordningen indad, og lad den krydse og næsten passere obturatormembranen. Sørg for, at anordningens håndtag er vendt, således at den lige spids på den spiralformede fører er i plan med kanalen på GYNECARE TVT ledeskinne, og at den forbliver vendt på denne måde, indtil spidsen krydser obturatormembranen (se figur 5).



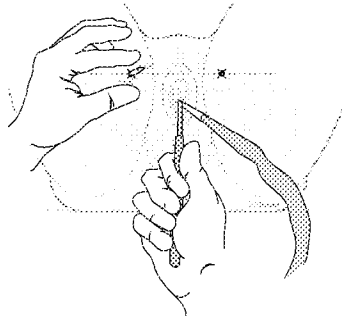
FIGUR 5

12. Når GYNECARE TVT ledeskinne med vinger er i denne stilling, fjernes den og holdes steril til senere brug på samme patient.



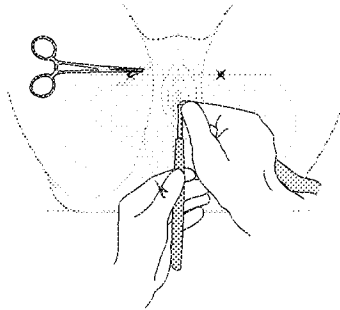
FIGUR 6

13. Når GYNECARE TVT ledeskinne med vinger er blevet fjernet, roteres håndtaget på den spiralformede fører samtidig med, at du bevæger håndtaget mod midtlinjen indtil det er vertikalt med gulvet (se figur 6). (Bemærk: Lad aldrig håndtaget vende horisontalt.)



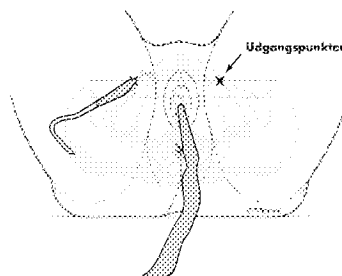
FIGUR 7

14. Den spiralformede førers spids bør komme ud nær de tidligere bestemte udgangspunkter (se figur 7). Det kan dog være nødvendigt med en let manipulering af huden. Hvis hudincisionen ikke allerede er foretaget, udføres den på det sted, hvor den spiralformede førers spids laver en bule i huden. Når spidsen af plastslangen stikker frem gennem hudåbningen, gribes plastslangens spids med en tang og, mens slangen stabiliseres nær urethra med tommelfingeren, fjernes den spiralformede fører med en omvendt rotation af håndtaget (se figur 8).



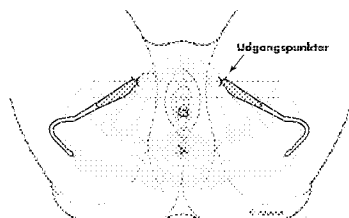
FIGUR 8

15. Træk plastslangen helt igennem huden, indtil båndet kommer til syne (se figur 9).



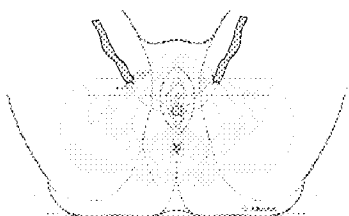
FIGUR 9

16. Gentag teknikken på patientens anden side og sørg for, at båndet ligger fladt under urethra (se figur 10).
(Bemærk: Hvis der opdages en snoning på båndet, skal man sørge for, at snoningen ikke placeres under urethra efter, at det overskydende bånd er trukket igennem.)



FIGUR 10

17. Når begge plastslanger er blevet trukket ud igennem hudincisionerne, skæres de af båndet og plasthylstrene. Anbring båndet løst, dvs. uden at stramme, og fladt under urethras midte. På dette stade kan der udføres en hostetest. Dette muliggør justering af båndet, således at kun få dråber urin udskilles, når patienten hoster (se figur 11).



FIGUR 11

Når båndet er på plads, fjernes plasthylstret, der dækker båndene. Placer et stumpt instrument (f.eks. en saks eller pincet) mellem urethra og båndet, mens plasthylstrene fjernes, eller brug en anden passende teknik ved udtagning af hylstrene, så det undgås at båndet strammes.

(Bemærk: For tidlig fjernelse af hylstret kan føre til, at efterfølgende justeringer bliver vanskelige.)

18. Efter justering af båndet lukkes den vaginale incision. Klip båndenderne af ved udgangspunkterne lige under huden på inderlåret. Luk hudincisionerne med sutur eller kirurgisk hudlim.
19. Cystoskopi kan udføres efter kirurgens skøn. Hvis cystoskopi blev udført efter den første indsætning, skal man sørge for, at blæren er tom, før indsættelsen påbegyndes på den anden side. Post-operativ oplægning af kateter à demeure er normalt ikke påkrævet. Patienten skal opfordres til at prøve at tømme blæren 2–3 timer efter operationen.

KONTRAINDIKATIONER

Som ved enhver suspensionsoperation bør dette indgreb ikke udføres på gravide patienter. Derudover bør det ikke anvendes på patienter med fremtidig vækspotentiale inklusiv kvinder, som har planer om at blive gravide, da PROLENE propylen-nettet ikke vil strække sig tilstrækkeligt.

ADVARSLER OG FORSIGTHEDSREGLER

- GYNECARE TVT obturatorproceduren må ikke anvendes på patienter, der er i anti-koagulationsbehandling.
- GYNECARE TVT obturatorproceduren må ikke anvendes på patienter, som har urinvejsinfektion.
- Brugere bør være bekendte med den kirurgiske teknik for urethrale suspensioner og være tilstrækkeligt uddannede i GYNECARE TVT obturatorproceduren, før GYNECARE TVT obturatoranordningen tages i brug.
- Korrekt kirurgisk praksis skal følges ved GYNECARE TVT obturatorproceduren og såvel som ved håndtering af kontaminerede eller inficerede sår.
- GYNECARE TVT obturatorproceduren skal udføres med omhu for at undgå at ramme store kar, nerver, blære og tarm. Opmærksomhed rettet mod patientanatomi og korrekt indsættelse af anordningen vil minimere risici.
- Blødning kan forekomme post-operativt. Hold øje med eventuelle symptomer eller tegn, for patienten sendes hjem fra hospitalet.
- Selvom det er usandsynligt, at beskadigelse af blæren vil forekomme med denne teknik, kan cystoskopi udføres efter kirurgens skøn.
- Plasthylstrene må ikke fjernes, før båndet er placeret korrekt.
- Sørg for, at båndet er anbragt uden stramning under urethras midterdel.
- Proceduren må ikke udføres, hvis du mistænker, at incisionsstedet er inficeret eller kontamineret.
- Eftersom der ikke findes kliniske oplysninger om graviditet efter sub-urethral slyngprocedure vha. GYNECARE TVT obturatorssystemet, skal patienten informeres om, at fremtidig graviditet kan gøre det kirurgiske indgreb virkningsløst, og at patienten kan risikere at blive inkontinent igen.

- Eftersom der ikke findes kliniske oplysninger om vaginal fødsel efter sub-urethral slyngeprocedure vha. GYNECARE TVT obturatorsystemet, bør kejsersnit overvejes i tilfælde af graviditet.
- Patienten skal informeres om at undgå at løfte tunge ting og/eller motionere (f.eks. cykling, jogging) i mindst tre til fire uger efter operationen og undgå samleje i en måned. Patienten kan sædvanligvis genoptage andre normale aktiviteter efter 1–2 uger.
- Patienten skal instrueres i at kontakte kirurgen straks, hvis der opstår dysuri, blødning eller andre problemer.
- Forbigående bensmerter, der varer 24–48 timer, kan forekomme og sædvanligvis behandles med et mildt analgetikum.
- Som ved andre inkontinensprocedurer, kan der opstå ny instabilitas af detrusor efter en sub-urethral slyngeprocedure vha. GYNECARE TVT obturatorsystemet. For at minimere risikoen skal man sørge for, at båndet placeres, som beskrevet ovenfor.
- PROLENE-nettet må ikke komme i kontakt med staplere, clips eller andre former for klemmer, da der kan opstå mekanisk skade på nettet.
- Hverken GYNECARE TVT obturatoranordningen eller dens komponenter må resteriliseres. Bortskaf åbnede, ubrugte anordninger.
- Profylaktisk antibiotika kan administreres i henhold til kirurgens sædvanlige praksis.

BIVIRKNINGER

- Punktering eller lacerationer af kar, nerver, blære, urethra eller tarm kan opstå under nålepassagen og kræve operation.
- Forbigående lokalirritation på sårstedet og en forbigående fremmedlegemereaktion kan forekomme. Denne reaktion kan resultere i udstødelse, erosion, fisteldannelse eller inflammation.
- Som ved alle fremmedlegemer kan PROLENE-nettet forværre en eksisterende infektion. Plasthylstrener, der i starten dækker PROLENE-nettet, er konstrueret til at minimere risikoen for kontaminering.
- Overkorrigering, dvs. hvis båndet strammes for meget, kan forårsage temporær eller vedvarende obstruktion af de nedre urinveje.

VIRKNINGER

Dyreforsøg har vist, at implantation af PROLENE-nettet fremkalder en minimal forbigående inflammatorisk reaktion i væv, som efterfølges af aflejring af et tyndt lag fibrøst væv, der kan vokse gennem maskerne i nettet og således inkorporere nettet i tilstødende væv. Materialet resorberes ikke, og det nedbrydes eller svækkes heller ikke af vævsenzymmer.

LEVERING

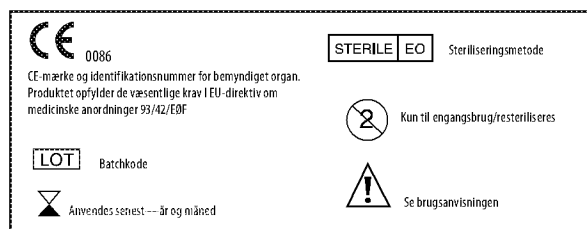
GYNECARE TVT obturatorsystemet leveres sterilt (ethylenoxid) til engangsbrug. Det må ikke resteriliseres. Genbrug af denne anordning (eller dele af denne anordning) kan skabe risiko for nedbrydning af produktet og krydskontaminering, hvilket kan lede til infektion eller overførsel af blodoverførte patogener til patienter og brugere. Må ikke anvendes, hvis emballagen er åbnet eller beskadiget. Kassér åbnede, ubrugte anordninger.

OPBEVARING

Det anbefales, at GYNECARE TVT obturatorsystemet til engangsbrug opbevares ved en temperatur under 25 °C, beskyttet mod fugt og direkte varme. Må ikke anvendes efter, at udløbsdatoen er overskredet.

FORSIGTIG: Gældende lov (i USA) begrænser salget af dette produkt til læger eller på ordination af en læge.

SYMBOLER ANVENDT VED MÆRKNING



NEDERLANDS**GYNECARE TVT™ obturatorsysteem
Spanningsvrij steunbandje tegen incontinentie****GYNECARE TVT obturator steunbandje,
voor eenmalig steriel gebruik****GYNECARE TVT obturator gebogen
inbrenginstrumenten, voor eenmalig
steriel gebruik****GYNECARE TVT obturator atraumatische vleugel-
applicatiegeleider, voor eenmalig
steriel gebruik****Lees alle informatie zorgvuldig.**

Indien men aanwijzingen niet nauwkeurig opvolgt, kan dit ondoelmatig functioneren van het hulpmiddel tot gevolg hebben en letsel veroorzaken.

Belangrijk:

Met deze bijsluiter wordt beoogd, aanwijzingen te verschaffen voor het gebruik van het GYNECARE TVT™ obturator systeem, met inbegrip van het GYNECARE TVT obturator steunbandje, de gebogen inbrenginstrumenten en de atraumatische vleugel-applicatiegeleider. Dit document behelst geen volledig overzicht van chirurgische technieken voor de behandeling van urinaire stressincontinentie. Het hulpmiddel mag uitsluitend worden gebruikt door artsen die een opleiding hebben genoten in de chirurgische behandeling van urinaire stressincontinentie (SUI) en, meer specifiek, in het implanteren van het GYNECARE TVT obturator steunbandje. Deze aanwijzingen hebben betrekking op het algemeen gebruik van het hulpmiddel. Het gebruik kan per procedure verschillen, naargelang de individuele operatietechniek en de anatomie van de patiënt.

BESCHRIJVING

Het GYNECARE TVT obturator systeem is een steriele procedurekit voor gebruik bij één patiënt. De kit bestaat uit:

GYNECARE TVT obturator steunbandje

Het GYNECARE TVT obturator steunbandje is een steriel hulpmiddel voor gebruik bij één patiënt, dat bestaat uit een stuk ongeverfd of blauw (ftalocyanineblauw, kleurindex 74160) PROLENE™ polypropyleen mesh-tape van ca. 1,1 cm x 45 cm, dat bekleed is met een plastic omhulsel met een overlapping in het midden. Aan beide uiteinden van de tape bevinden zich plastic slangaansluitingen. PROLENE polypropyleen mesh is opgebouwd uit gebreide filamenten van geëxtrudeerde polypropyleen strengen waarvan de samenstelling identiek is aan die van de strengen in PROLENE polypropyleen niet-resorbeerbare chirurgische hechtmaterialen. Vastgesteld is dat dit materiaal bij gebruik als hechtmateriaal niet reactief is en dat het bij klinisch gebruik zijn kracht voor onbeperkte tijd behoudt. PROLENE mesh wordt gebreed met gebruikmaking van een proces waarbij alle knooppunten van de vezels onderling met elkaar verbonden zijn en waardoor in beide richtingen elasticiteit wordt verschaft. Deze eigenschap van tweerichtingselasticiteit maakt adaptatie mogelijk aan diverse spanningen die in het lichaam worden ondervonden.

GYNECARE TVT gebogen inbrenginstrumenten

De GYNECARE TVT inbrenginstrumenten zijn twee roestvrijstalen, gebogen draaddoorhaal-instrumenten met plastic handvatten. De instrumenten zijn speciaal ontworpen voor het aanbrengen van het GYNECARE TVT obturator steunbandje. De inbrenginstrumenten worden geleverd in tweetallen voor bediening met de linker- en rechterhand, en zijn tevoren geassembleerd met het GYNECARE TVT obturator steunbandje. De inbrenginstrumenten MOGEN op generlei wijze worden verbogen of anderszins vervormd.

GYNECARE TVT atraumatische vleugel-applicatiegeleider

De GYNECARE TVT atraumatische vleugel-applicatiegeleider is een roestvrijstalen hulpinstrument, waarmee de doorgang van de GYNECARE TVT gebogen inbrenginstrumenten door het weefselpreparatietraject wordt vergemakkelijkt.

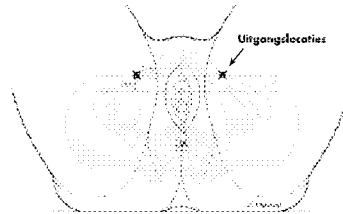
INDICATIES

Het GYNECARE TVT obturator steunbandje is bedoeld voor toepassing bij vrouwen als sub-urethrale suspensieband voor de behandeling van urinaire stressincontinentie, voorkomend uit hypermobilität van de urethra en/of door intrinsieke sfincterinsufficiëntie.

GEBRUIKSAANWIJZING

(Opmerking: De in de illustraties getoonde handposities zijn niet eenduidig dwingend.)

1. Leg de patiënt dorsaal in lithotomiepositie, met de heupen in hyperflexie ten opzichte van het abdomen. De billen moeten op hetzelfde niveau als de rand van de operatietafel zijn gepositioneerd.
2. De procedure kan onder lokale, regionale of algehele anesthesie worden uitgevoerd.
3. Trek zo nodig de schaamlippen terug om het behandelgebied beter te prepareren.
4. Breng een urethra-katheter in de blaas in en ledig de blaas.
5. Markeer de uitganglocaties van de plastic buisjes door een horizontale lijn te trekken op het niveau van de urethramond en een tweede lijn evenwijdig aan de eerste en 2 cm daarboven. Lokaliseer de uitganglocaties op deze lijn, 2 cm lateraal van de dijbeenplooien (de huid kan worden afgevlakt door deze strak te trekken). Markeer de uitganglocaties. Ook kan op beide uitgangspunten een incisie van 5 mm–10 mm worden gemaakt, op dit tijdstip of in een latere procedurefase (zie figuur 1).

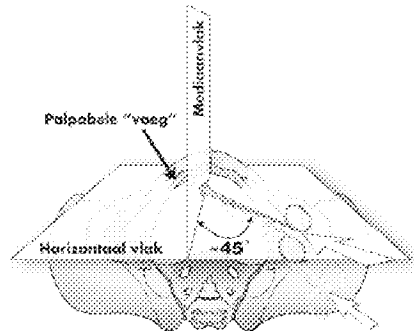


FIGUUR 1

6. Maak, met gebruikmaking van Allis klemmen voor de tractie, een mediale incisie van 1 cm in het vaginaslijmvlies, beginnende op 1 cm proximaal van de urethramond.

(Opmerking: Aanbevolen wordt, het inbrengen van het steunbandje aan één kant te voltooien voordat begonnen wordt met het prepareren van de andere kant.)

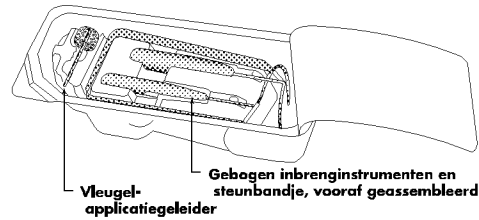
Voer stompe dissectie uit door na aanvankelijke scherpe dissectie een “duw-en-spreidtechniek” toe te passen, bij voorkeur met een puntige, gebogen schaar. Het laterale preparatietraject moet een oriëntatie hebben van 45° ten opzichte van mediaal, en de schaar moet daarbij horizontaal zijn georiënteerd (zie figuur 2). Ga verder met losprepareren in de richting van de voeg tussen de romp van het schaambeent en het os pubis ramus inferior (zie figuur 2).



FIGUUR 2

Bij het bereiken van de voeg tussen de romp van het schaambeent en het os pubis ramus inferior moet het membraan van de obturator worden doorboord. Daarbij kan weerstandsvermindering voelbaar zijn. Het kanaal moet een diameter van ca. 5 mm–7 mm hebben en mag niet meer dan 5 cm diep zijn. Indien dieper dan 5 cm wordt losgeprepareerd, bestaat het gevaar van onbedoelde toegang tot de Retzius-ruimte. Controleer of onder de juiste hoek is geprepareerd indien het bot na 5 cm dissectie nog niet is bereikt.

7. Neem de inwendige verpakingsmodule uit de buitenverpakking. Neem vervolgens de GYNECARE TVT vleugel-applicatiegeleider uit de verpakingsmodule (zie figuur 3).



FIGUUR 3

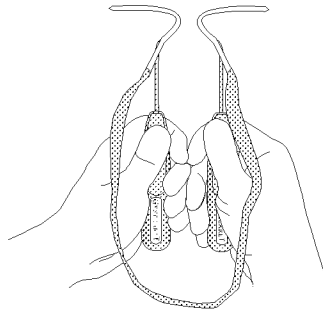
8. Breng de GYNECARE TVT vleugel-applicatiegeleider in het losgeprepareerde weefselkanaal in totdat de geleider het os pubis "ramus inferior" passeert en in de vooraf gemaakte opening in het obturatorembraan doordringt. Bij het doorsteken van het obturatorembraan door de applicatiegeleider kan weerstandsvermindering voelbaar zijn.

Indien het inbrengen van de applicatiegeleider problemen oplevert, moet de oriëntatie van het traject van de prepareerschaar opnieuw worden gecontroleerd.

(Opmerking: De applicatiegeleider moet met de open zijde naar de chirurg zijn gericht. Indien nodig kan de flexibele tip van worden gebogen om de lengte van de geleider te vergroten; zie figuur 5.)

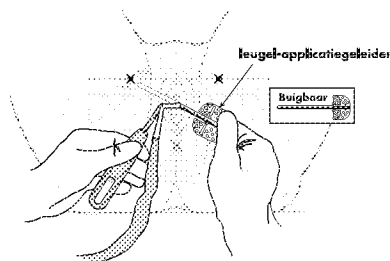
9. Neem de GYNECARE TVT gebogen inbrenginstrumenten met het GYNECARE TVT obturator steunbandje uit de steriele verpakking (zie figuur 3 voor samenstelling).

(Opmerking: Om zeker te zijn van een juiste oriëntatie van de gebogen inbrenginstrumenten en het steunbandje dient men zich ervan te overtuigen dat het GYNECARE logo de duimafdruk op de plastic handgreep naar de chirurg zijn gericht en dat de punten aan de buitenkant liggen, eveneens naar de chirurg gericht. Rechts van de mediaanlijn van het lichaam van de patiënt wordt gewerkt met het inbrenginstrument in de linkerhand van de chirurg; zie figuur 4.)



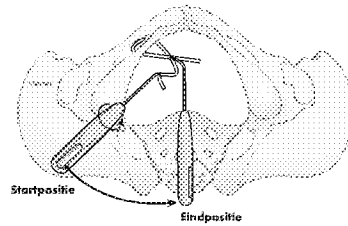
FIGUUR 4

10. Leg een van de gebogen inbrenginstrumenten op de steriele afdekdoek of op een andere geschikte steriele plek, totdat u dit instrument nodig hebt. Verzekert u ervan dat het steunbandje niet is gespiraliseerd.
11. Breng het juiste GYNECARE TVT inbrenginstrument in het losgeprepareerde kanaal in, volgens hetzelfde traject als de GYNECARE TVT applicatiegeleider. Duw het steunbandje heen en weer draaiend naar binnen tot iets voorbij het obturatorembraan. Zorg dat de handgreep van het inbrenginstrument zodanig is georiënteerd dat de rechte tip van het gebogen inbrenginstrument lijnt met het kanaal in de GYNECARE TVT vleugel-applicatiegeleider, en in die oriëntatie gehandhaafd blijft totdat de tip het obturatorembraan doorboort (zie figuur 5).



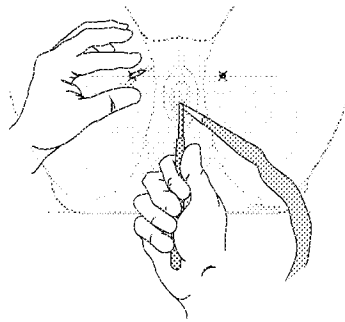
FIGUUR 5

12. Verwijder na het bereiken van deze positie de GYNECARE TVT applicatiegeleider en houd deze steriel zodat de geleider later weer op dezelfde patiënt kan worden gebruikt.



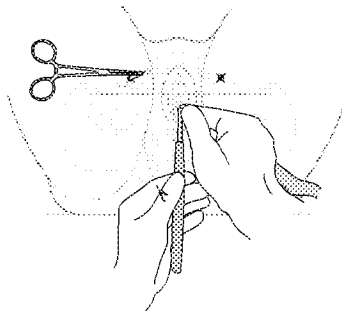
FIGUUR 6

13. Draai, na verwijdering van de GYNECARE TVT applicatiegeleider, de handgreep van het inbrenginstrument en beweeg de handgreep tegelijkertijd in de richting van de mediaanlijn totdat de handgreep verticaal is gepositioneerd (zie figuur 6). **(N.B.: Laat de handgreep nooit een horizontale positie aannemen.)**



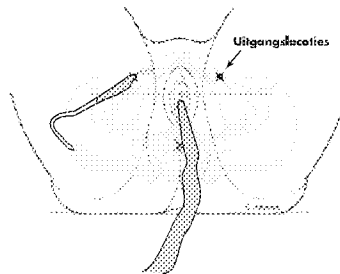
FIGUUR 7

14. De punt van het inbrenginstrument moet de buikwand verlaten dicht bij de vooraf bepaalde uitganglocatie (zie figuur 7). Hierbij kan echter enige huidmanipulatie nodig zijn. Indien tevoren geen huidincisie is gemaakt, moet deze nu worden gemaakt op de plek waar de tip van het inbrenginstrument de huid omhoog duwt. Pak het puntige uiteinde van het plastic buisje met een klem vast wanneer het uiteinde in de huidopening te voorschijn komt en neem het inbrenginstrument uit door de handgreep in omgekeerde richting te roteren, terwijl u het buisje naast de urethra met de duim stabiliseert (zie figuur 8).



FIGUUR 8

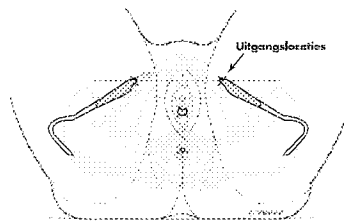
15. Trek het plastic buisje geheel door de huid totdat het steunbandje verschijnt (zie figuur 9).



FIGUUR 9

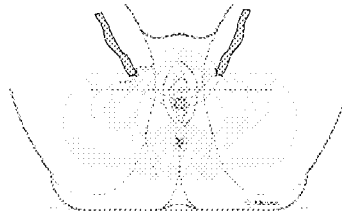
16. Herhaal de beschreven procedure aan de andere lichaamszijde van de patiënt en zorg er daarbij voor dat het bandje plat onder de urethra blijft liggen (zie figuur 10).

(Opmerking: Indien u in het bandje een draaiing ontdekt, moet het bandje zodanig worden gepositioneerd dat de draaiing zich niet onder de urethra bevindt nadat de extra lengte van het bandje door de tweede opening is getrokken.)



FIGUUR 10

17. Wanneer de beide plastic buisjes door de huidincisies zijn getrokken, worden de buisjes van het bandje en van de plastic omhulsels losgeknipt. Zorg dat het bandje losjes, d.w.z. zonder spanning, en plat onder het middengedeelte van de urethra komt te liggen. In deze procedurefase kan een hoesttest worden uitgevoerd. Hierbij kan de trekspanning van het bandje worden bijgesteld, zodat bij het hoesten slechts enkele druppels urine worden verloren (zie figuur 11).



FIGUUR 11

Wanneer het bandje de juiste positie heeft, wordt de plastic hoes die het bandje omhult verwijderd. Om te voorkomen dat het bandje spanning ondervindt, moet tijdens het verwijderen van het omhulsel een stomp instrument (b.v. een schaar of pincet) of een ander geschikt voorwerp tussen de urethra en het bandje worden geplaatst.

(Opmerking: Door voortijdige verwijdering van het omhulsel zouden later uit te voeren bijstellingen worden bemoeilijkt.)

18. Sluit de vagina-incisie nadat het bandje goed is gesteld. Knip de uiteinden van het bandje bij de uitgangslocaties af, net onder de huid van het binnendijsbeen. Sluit de huidincisies met hechtdraad of chirurgische hechtpasta.
19. Naar beoordeling van de chirurg kan cystoscopie worden uitgevoerd. Indien na de eerste insertie cystoscopie is uitgevoerd, moet de blaas worden geledigd voordat met de insertie aan de tweede lichaamszijde wordt begonnen. Postoperatieve verblijfskatheterisatie is doorgaans niet nodig. De patiënt moet worden aangemoedigd, 2–3 uur na de operatie een poging tot blaaslediging te doen.

CONTRA-INDICATIES

Zoals voor alle suspensieprocedures geldt, dient deze ingreep niet te worden uitgevoerd bij zwangere patiënten. Daar de PROLENE polypropyleen mesh niet significant uitrekbaar is, dient deze ingreep bovendien niet te worden uitgevoerd bij onvolgroeide patiënten en bij patiënten met zwangerschapsplannen.

WAARSCHUWINGEN EN VOORZORGSMATREGELEN

- Pas de GYNECARE TVT obturator procedure niet toe bij patiënten die behandeld worden met anticoagulantia.
- Pas de GYNECARE TVT obturator procedure niet toe bij patiënten met een urineweginfectie.
- De gebruiker moet vertrouwd zijn met chirurgische urethrasuspensietechnieken en moet zich afdoende hebben bekwaamd in de uitvoering van de GYNECARE TVT obturator procedure voordat hij/zij het GYNECARE TVT obturator steunbandje daadwerkelijk aanbrengt.
- Bij het uitvoeren van de GYNECARE TVT obturator procedure en bij de behandeling van besmette of geïnfecteerde wonden moet gebruik worden gemaakt van algemeen aanvaarde chirurgische praktijkmethoden.
- Bij het uitvoeren van de GYNECARE TVT obturator procedure moet contact met grote bloedvaten, zenuwen, blaas en darmen zorgvuldig worden vermeden. Door aandacht te besteden aan de anatomie van de patiënt en aan het correct inbrengen van het steunbandje houdt men de risico's minimaal.
- Er kan postoperatieve bloeding optreden. Controleer of er hiervan symptomen of indicaties zijn voordat de patiënt uit het ziekenhuis wordt ontslagen.
- Hoewel blaasletsels bij deze methode onwaarschijnlijk is, kan naar beoordeling van de chirurg cystoscopie worden uitgevoerd.
- Verwijder het plastic omhulsel pas nadat het steunbandje goed is gepositioneerd.
- Zorg ervoor dat het steunbandje spanningsloos onder het middengedeelte van de urethra geplaatst wordt.
- Voer deze procedure niet uit indien er verdenking bestaat van infectie of besmetting van het te behandelen gebied.
- Er is geen klinische informatie beschikbaar over zwangerschappen na procedures met sub-uretrale suspensiebandjes met gebruikmaking van het GYNECARE TVT obturator systeem. Daarom moet de patiënt van de mogelijkheid op de hoogte worden gesteld dat toekomstige zwangerschappen de effecten van de chirurgische procedure teniet kunnen doen en dat de incontinentie in zo'n geval kan recidiveren.
- Aangezien er geen klinische gegevens bekend zijn over vaginale partus na procedures met sub-uretrale suspensiebandjes met gebruikmaking van het GYNECARE TVT obturator systeem, moet in geval van zwangerschap een geboorte middels sectio caesarea worden overwogen.
- De patiënt moet worden geïnstrueerd om na de operatie ten minste drie tot vier weken geen zware objecten te tillen en/of andere lichamelijke inspanningen te leveren (b.v. fietsen of joggen), en om gedurende een maand geen seksuele omgang te hebben. Doorgaans kan de patiënt na een of twee weken haar overige normale activiteiten hervatten.
- De patiënt moet worden geïnstrueerd, onmiddellijk met de chirurg contact op te nemen indien dysurie, bloeding of andere problemen optreden.
- Gedurende 24–48 uur postoperatief kan voorbijgaande pijn in de benen optreden. Deze kan doorgaans worden behandeld met lichte pijnstillers.
- Evenals bij andere incontinentieprocedures het geval is, kan na een procedure met sub-uretrale suspensiebandjes met gebruikmaking van het GYNECARE TVT obturator systeem de novo detrusor-instabiliteit optreden. Dit risico kan worden verkleind door het nauwgezet volgen van de hierboven beschreven plaatsingsmethode.
- Laat het PROLENE mesh niet in aanraking komen met nietjes, clips of klemmetjes, aangezien het daardoor mechanische schade kan oplopen.
- Steriliseer het GYNECARE TVT obturator steunbandje of andere systeemcomponenten niet opnieuw. Werp geopende en niet gebruikte hulpmiddelen weg.
- Overeenkomstig de gebruikelijke praktijkmethoden van de chirurg kunnen profylactische antibiotica worden toegediend.

BIJWERKINGEN

- Tijdens het inbrengen van de naald kan zich punctuur of laceratie van bloedvaten, zenuwen, blaas of darmen voordoen. Dit vergt mogelijk operatieve reparatie.
- Er kan sprake zijn van lokale irritatie bij het wondgebied en van overgevoeligheidsreacties op lichaamsvreemde materialen, beide van voorbijgaande aard. Dergelijke reacties kunnen extrusie, erosie, fistelvorming en inflammatie tot gevolg hebben.
- Zoals met alle lichaamsvreemde voorwerpen het geval is, kan PROLENE mesh een bestaande infectie verergeren. Het plastic omhulsel waarmee de PROLENE mesh aanvankelijk is bekleed dient ter beperking van het risico van besmetting.
- Indien er te krachtig wordt gecorrigeerd, d.w.z. als er te veel spanning op het bandje wordt uitgeoefend, kan dit een tijdelijke of permanente obstructie van het onderste gedeelte van de urinewegen veroorzaken.

WERKINGEN

Onderzoek op dieren heeft aangetoond dat implantatie van PROLENE mesh een minimale ontstekingsreactie in de weefsels teweegbrengt. Deze is van voorbijgaande aard en wordt gevolgd door afzetting van een dunne fibreuze weefsellaag die door de mazen van de mesh groeit en de mesh zo in het omliggende weefsel opneemt. Het materiaal wordt niet geabsorbeerd en is evenmin onderhevig aan afbreking of verzwakking door de werking van weefselenzymen.

LEVERING

Het GYNECARE TVT obturator systeem wordt steriel geleverd (ethyleenoxide), voor eenmalig gebruik. Steriliseer het product niet opnieuw. Opnieuw gebruiken van dit instrument (of onderdelen hiervan) kan een risico van productafbraak en kruisbesmetting veroorzaken, hetgeen kan leiden tot overdracht van bloed-overdraagbare pathogenen aan patiënten en gebruikers. Gebruik het product niet wanneer de verpakking geopend of beschadigd is. Werp geopende en niet gebruikte hulpmiddelen weg.

OPSLAG

De aanbevolen opslagvoorwaarden voor het GYNECARE TVT obturator systeem voor eenmalig gebruik zijn: temperatuur maximaal 25 °C, op veilige afstand van vocht of directe hitte. Gebruik het product niet na het verstrijken van de uiterste gebruiksdatum.

LET OP: Krachtens de federale wetgeving (in de Verenigde Staten van Amerika) mag dit hulpmiddel uitsluitend door of in opdracht van een arts worden verkocht.

SYMBOLEN OP DE ETIKETTEN



SUOMI

**GYNECARE TVT™ -obturaattorijärjestelmä
Jännityksetön tuki inkontinenssin hoitoon****GYNECARE TVT -obturaattori,
steriili ja kertakäyttöinen****GYNECARE TVT -obturaattorin kääntyvät asettimet,
steriilit ja kertakäyttöiset****GYNECARE TVT -obturaattorin atraumaattinen,
siivekkeellinen ohjain, steriili
ja kertakäyttöinen****Lue kaikki ohjeet huolellisesti.**

Ohjeiden laiminlyönti voi johtaa laitteen toimintahäiriöön ja aiheuttaa vamman.

Tärkeää:

Tässä tuoteselosteessa annetaan GYNECARE TVT™ -obturaattorijärjestelmän käyttöä koskevia ohjeita. Järjestelmään kuuluvat mm. GYNECARE TVT -obturaattori, kääntyvät asettimet ja atraumaattinen, siivekkeellinen ohjain. Siinä ei anneta yksityiskohtaisia ponnistusinkontinenssin kirurgista korjausmenetelmää koskevia ohjeita. Laitetta saavat käyttää ainoastaan lääkärit, joilla on kokemusta ponnistusinkontinenssin kirurgisista hoitomenetelmistä ja erityisesti GYNECARE TVT -obturaattorin implantoinnista. Nämä ohjeet ovat yleisiä laitteen käyttöä koskevia ohjeita. Käyttö voi vaihdella tietyissä toimenpiteissä kirurgin menetelmän ja potilaan anatomian mukaisesti.

KUVAUS

GYNECARE TVT -obturaattorijärjestelmä on steriili, potilaskohtainen toimenpidepakkaus, joka sisältää seuraavat osat:

GYNECARE TVT -obturaattori

GYNECARE TVT -obturaattori on steriili, potilaskohtainen laite, johon kuuluu yksiosainen värjäämätön tai siniseksi värjätty (ftalosyaaniinisinen, värinumero 74160), noin 1,1 cm x 45 cm:n kokoinen PROLENE™-polypropyleeniverkkonauha, jota suojaa nauhan keskellä päällekkäin menevä muovisuojaus. Nauhan molemmissa päissä on muoviputkikiinnittimet. PROLENE-polypropyleeniverkko muodostuu polypropyleenisäikeistä kudotusta langasta, jonka tyyppistä käytetään resorboitumattomassa PROLENE-ommellangassa. Tämän materiaalin ei ole todettu ommellankana käytettäessä aiheuttavan kudoreaktioita ja se pysyy kliinisessä käytössä pysyvästi muuttumattomana. PROLENE-verkko on kudottu menetelmällä, joka liittyy yhteen jokaisen säikeen haaran, minkä ansiosta se joustaa molempiin suuntiin. Tämän kaksisuuntaisen joustavuuden ansiosta verkko mukautuu erilaisiin kehon rasituksiin.

Kääntyvät GYNECARE TVT -asettimet

Kääntyvät GYNECARE TVT -asettimet ovat ruostumattomasta teräslangasta valmistetut kaarevat asettimet. Niissä on muovikahvat, joiden avulla GYNECARE TVT -obturaattori viedään sisään. Asettimiä on yksi vasemman- ja yksi oikeanpuoleinen yksikkö ja ne toimitetaan valmiiksi GYNECARE TVT -obturaattoriin kiinnitettynä. Kääntyvää asetinta ELSAA taivuttaa tai vääntää millään tavalla.

Atraumaattinen, siivekkeellinen GYNECARE TVT -ohjain

Atraumaattinen, siivekkeellinen GYNECARE TVT -ohjain on ruostumattomasta teräksestä valmistettu instrumentti, jota käytetään apuna kääntyvien GYNECARE TVT -asettimien sisäänvientiin dissektiokanavan läpi.

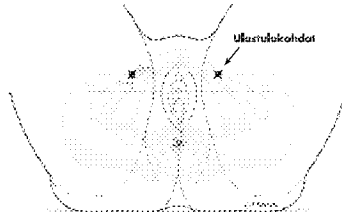
INDIKAATIOT

GYNECARE TVT -obturaattoria käytetään naisilla virtsaputken alapuolisena tukinauhana virtsaputken hypermobiliiteetin ja/tai sisemmän sulkijalihaksen heikkouden aiheuttaman ponnistusinkontinenssin hoidossa.

KÄYTTÖOHJEET

(Huomautus: Kuvisa esitetyt käsien asennot voivat vaihdella.)

1. Sijoita potilas selinmaalle (dorsaalinen litotomia-asento) jalat kohotettuina ja lonkat vatsan päällä. Istumalihasten on oltava pöydän reunan tasalla.
2. Toimenpide voidaan suorittaa paikallis- tai johtopuudutuksessa tai yleisanestesiassa.
3. Labia voidaan haluttaessa levittää paremman näkyvyyden aikaansaamiseksi.
4. Vie virtsaputkikatetri virtsarakkoon ja tyhjennä virtsarakko.
5. Merkitse muoviputkien ulostulokohdat vetämällä vaakasuora viiva virtsaputken aukon tasolle ja toinen samansuuntainen viiva 2 cm ensimmäisen viivan yläpuolelle. Paikanna ulostulokohdat tällä viivalla, 2 cm lateraalisesti reisien taitoskohtaan nähden (iho voidaan tasoittaa venyttämällä). Merkitse ulostulokohdat ihoon tai tee vaihtoehtoisesti molempiin ulostulokohtiin 5 mm – 10 mm:n avausviilto tässä vaiheessa tai toimenpiteen myöhemmässä vaiheessa (katso kuvaa 1).

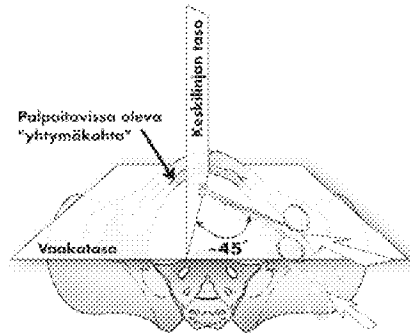


KUVA 1

6. Käytä Allis-puristimia vetoapuna ja tee 1 cm keskilinjaa viilto emättimen limakalvoon alkaen noin 1 cm:n etäisyydeltä virtsaputken ulkoaukon proksimaalipuolella.

(Huomautus: Suosittelemme, että laite viedään sisään ensin toiselta puolelta ennen vastakkaisen puolen dissektion tekemistä.)

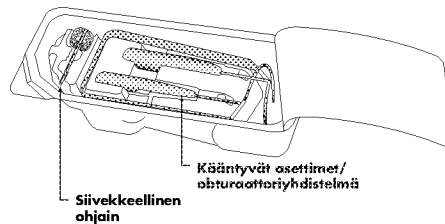
Kun avausviilto on tehty, tyllppää dissektiotoimenpidettä jatketaan "työntö-levitysmenetelmää" käyttäen teräviä, kaarevia saksiä käyttäen. Lateraalinen dissektioireitti on suunnattava 45°:n kulmaan keskilinjalta niin, että sakset ovat vaakatasossa (kuva 2). Jatka dissektiota häpyluun rungon ja alemman haarakohdan yhtymäkohtaa kohti (kuva 2).



KUVA 2

Kun häpyluun rungon ja alemman haarakohdan yhtymäkohta saavutetaan, puhkaise obturaattorin kalvo. Vastus vähenee, kun kalvo on perforoitu. Kanavan on oltava läpimitaltaan noin 5 mm–7 mm ja korkeintaan 5 cm pitkä. Yli 5 cm pitkä dissektio voi aiheuttaa tahattoman sisäänmenon häpyluun ja virtsarakon väliseen tilaan. Jos luuta ei saavuteta vaikka aluetta on dissekoitu 5 cm:n pituudelta, tarkista onko dissektiokulma oikea.

7. Poista sisäpakkauksessa oleva työasema ulkopakkauksesta. Ota sen jälkeen siivekkeellinen GYNECARE TVT -ohjain pakkauksesta (kuva 3).



KUVA 3

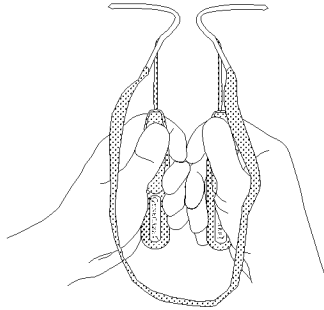
8. Työnä siivekkeellistä GYNECARE TVT -ohjainta dissektiokanavaan, kunnes se ohittaa häpyluun alemman haarakohdan ja menee sisään aiemmin obturaattorin kalvoon perforoidusta aukosta. Vastus vähenee, kun siivekkeellinen ohjain työntyy obturaattorin kalvon läpi.

Jos ohjainta työnnettäessä tuntuu vastusta, varmista kanavan suunta saksien avulla.

(Huomautus: Ohjaimen avoimen puolen on osoitettava kirurgia kohti. Taitettavaa siivekettä voidaan taittaa ohjaimen työskentelypituuden lisäämiseksi tarvittaessa kuvan 5 mukaisesti.)

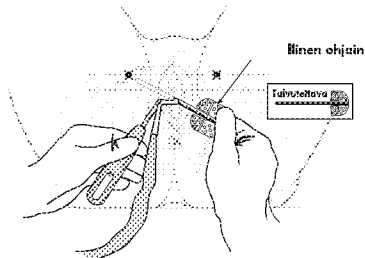
9. Ota kääntyvät GYNECARE TVT -asettimet ja GYNECARE TVT -obturaattori steriilistä pakkauksesta (osat esitetty kuvassa 3).

(Huomautus: Kääntyvät asettimet ja nauha on suunnattu oikein, kun muovikahvojen GYNECARE-logo ja peukalosyvennys osoittavat kirurgia kohti ja asettimien kärjet ovat muoviputkien ulkopuolella ja osoittavat kirurgia kohti. Kirurgin vasemmassa kädessä olevaa asetinta käytetään potilaan oikealla puolella kuvan 4 esittämällä tavalla.)



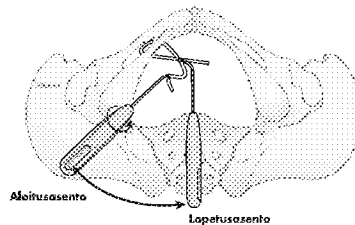
KUVA 4

10. Aseta toinen kääntyvästä asettimista steriilille liinalle tai muulle asianmukaiselle steriilille alueelle odottamaan käyttöä. Varmista, ettei nauha ole kiertynyt.
11. Vie oikea kääntyvä GYNECARE TVT -asetin dissektiokanavaan siivekkeellisen GYNECARE TVT -ohjaimen muodostamaa kanavaa pitkin. Työnnä laitetta sisäänpäin jonkin verran obturaattorin kalvon läpi. Varmista, että laitteen kahva on suunnattu suoraan niin, että kääntyvän asettimen suora kärki on kohdakkain siivekkeellisen GYNECARE TVT -ohjaimen kanavan kanssa ja pysyy paikallaan kunnes kärki on mennyt obturaattorin kalvon läpi (kuva 5).



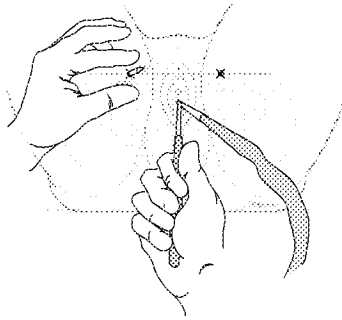
KUVA 5

12. Kun asetin on tässä asennossa, poista siivekkeellinen GYNECARE TVT -ohjain ja pidä sitä steriilillä alueella myöhempää vastakkaisen puolen toimenpidettä varten samalla potilaalla.



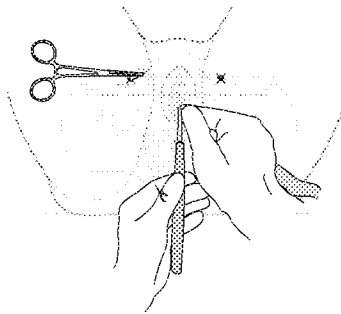
KUVA 6

13. Kun siivekkeellinen GYNECARE TVT -ohjain on poistettu, käännä asettimen kahvaa samalla, kun siirryt keskilinjaa kohti, kunnes kahva on kohtisuorassa lattiaan nähden (kuva 6). **(Huomautus: Kahvaa ei saa asettaa vaakasuoraan.)**



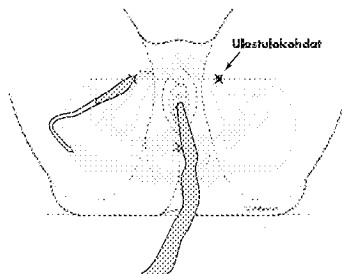
KUVA 7

14. Kääntyvän asettimen kärjen on tultava ulos lähellä aiemmin merkittyä ulostulokohtaa (kuva 7). Ihoa voidaan kuitenkin joutua siirtämään jonkin verran. Jos avausviiltoa ei ole vielä tehty, tee avausviilto siihen kohtaan, jossa asettimen kärki työntyy ulospäin ihon alla. Kun muoviputken kärki tulee ulos avausviiltosta, tartu sen kärkeen puristimella ja poista asetin kääntämällä kahvaa vastakkaiseen suuntaan ja pitämällä putkea samalla paikallaan peukalon avulla virtsaputken lähellä (kuva 8).



KUVA 8

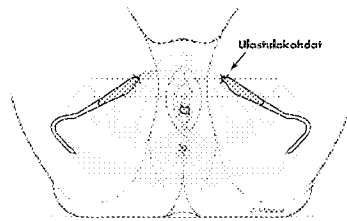
15. Vedä muoviputki kokonaan ihon läpi, kunnes nauha tulee esiin ihovillilosta (kuva 9).



KUVA 9

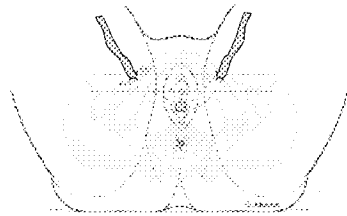
16. Toista toimenpide vastakkaisella puolella ja varmista, että nauha pysyy suorassa virtsaputken alapuolella (kuva 10).

(Huomautus: Jos huomaat, että nauha on kääntynyt, varmista ettei kääntynyttä nauhaa jää virtsaputken alapuolelle sen jälkeen, kun ylimääräinen nauhaosa vedetään pois potilaasta.)



KUVA 10

17. Kun molemmat muoviputket on vedetty pois ihoviiltojen kautta, katkaise muoviputket nauhasta ja sitä suojaavasta muovisuojuksesta. Sijoita nauha löysälle, niin ettei se kiristä yhtään ja on suorassa, virtsaputken keskiosan alapuolelle. Tässä vaiheessa voidaan suorittaa yskäystesti. Testin avulla nauhaa voidaan säätää niin, että ainoastaan muutama tippa virtsaa karkaa yskäisyn aikana (kuva 11).



KUVA 11

Kun nauha on paikallaan, poista sitä suojaava muovisuojaus. Aseta tylppä instrumentti (esim. sakset tai pihdit) virtsaputken ja nauhan väliin muovisuojusten poistamisen aikana tai käytä muuta asianmukaista suojusten poistomenetelmää välttämällä kiristämistä nauhaa.

(Huomautus: Muovisuojuksen ennenaikainen poisto voi vaikeuttaa poistonjälkeistä nauhan kireyden säätöä.)

18. Kun nauhan säädöt on tehty, sulje emättimeen tehty avausviilto. Katkaise nauhan päät ulostulokohdissa aivan sisäreiden ihon alapuolelta. Sulje avausviillot ompelein tai kirurgisella kudoslaimalla.
19. Kystokopia voidaan suorittaa kirurgin harkinnan mukaisesti. Jos kystokopia suoritettiin nauhan ensimmäisen puolen sisäänviennin jälkeen, varmista että virtsarakko tyhjenetään ennen nauhan toisen puolen sisäänvientiä. Leikkauksenjälkeistä katetrointia ei yleensä tarvita. Potilasta on kehoitettava yrittämään virtsarakon tyhjentämistä 2–3 tuntia leikkauksen jälkeen.

KONTRAINDIKAATIOT

Kuten minkä tahansa suspensiokirurgian ollessa kyseessä, tätä toimenpidettä ei saa suorittaa raskaana olevalle potilaalle. Tämän lisäksi, koska PROLENE-polypropyleeniverkko ei veny huomattavassa määrin, toimenpidettä ei saa suorittaa vielä kasvaville potilaille, mukaan lukien raskautta suunnitteleville naisille.

VAROITUKSET JA VAROTOIMET

- GYNECARE TVT -obturaattoritoimenpidettä ei saa suorittaa potilaille, joille annetaan antikoagulanttihoitoa.
- GYNECARE TVT -obturaattoritoimenpidettä ei saa suorittaa potilaille, joilla on virtsatietulehdus.
- Toimenpiteen suorittajien on tunnettava virtsaputken suspensiotoimenpiteet ja heillä on oltava riittävä GYNECARE TVT -obturaattoritoimenpidettä koskeva koulutus ennen GYNECARE TVT -obturaattorin käyttöä.
- GYNECARE TVT -obturaattoritoimenpiteen yhteydessä on noudatettava hyväksyttyjä kirurgisia toimenpiteitä sekä kontaminoituneita ja tulehtuneita haavoja koskevaa käytäntöä.
- GYNECARE TVT -obturaattoritoimenpide on suoritettava huolellisesti ja suuria verisuonia, hermoja, virtsarakkoa ja suolistoa välttämällä. Riskit minimoidaan kiinnittämällä huomio potilaan anatomiaan ja laitteen asianmukaiseen sisäänvientiin.
- Leikkauksen jälkeen voi esiintyä verenvuotoa. Kaikkia oireita tai merkkejä on seurattava ennen kuin potilas päästetään pois sairaalasta.
- Vaikka virtsarakon vaurio on epätodennäköistä tämän menetelmän yhteydessä, kirurgi voi harkintansa mukaan suorittaa kystoskopisen tutkimuksen.
- Muovisuojusta ei saa poistaa ennen kuin nauha on asetettu kunnolla paikoilleen.
- Varmista, että nauha kulkee virtsaputken keskiosan alapuolelta eikä ole kireällä.
- Tätä toimenpidettä ei saa suorittaa, jos kirurgisen toimenpidealueen epäillään olevan tulehtunut tai kontaminoitunut.

- Koska saatavilla ei ole tietoa virtsaputkenalaisen nauhatoimenpiteen vaikutuksista myöhemmän raskauteen GYNECARE TVT -obturaattorijärjestelmää käytettäessä, potilasta on muistutettava siitä, että mahdolliset tulevat raskaudet voivat mitätöidä toimenpiteen vaikutukset ja aiheuttaa inkontinenssin palautumisen.
- Koska saatavilla ei ole kliinistä tietoa virtsaputkenalaisen nauhatoimenpiteen jälkeisestä alatiesynnytyksestä GYNECARE TVT -obturaattorijärjestelmää käytettäessä, mahdollisen raskauden yhteydessä on harkittava sektiota.
- Leikkauksen jälkeen potilasta on kehoitettava välttämään raskaiden esineiden nostamista ja/tai rasittavia kuntoharjoituksia (esim. pyöräily ja hölkkä) vähintään kolmen-neljän viikon ajan sekä yhdyntää kuukauden ajan. Potilas voi tavallisesti suorittaa muita normaaleja toimia taas yhden-kahden viikon kuluttua.
- Potilasta on kehoitettava ottamaan välittömästi yhteyttä kirurgiin, jos hänellä esiintyy kipua virtsatessa, verenvuotoa tai muita ongelmia.
- Ohimenevää kipua voi esiintyä alaraajoissa noin 24–48 tunnin ajan ja se voidaan normaalisti hallita kipulääkityksellä.
- Kuten kaikkien inkontinenssitoimenpiteiden yhteydessä, de novo -tyhjentäjälihakseen instabiileettia voi esiintyä virtsaputkenalaisen nauhatoimenpiteen jälkeen GYNECARE TVT -obturaattorijärjestelmää käytettäessä. Tämän riskin minimoimiseksi nauha on implantoitava potilaaseen yllä kuvattujen ohjeiden mukaisesti.
- PROLENE-verkko ei saa koskettaa haksia, klipsejä tai puristimia, sillä ne voivat aiheuttaa verkon mekaanisia vaurioita.
- GYNECARE TVT -obturaattoria tai sen osia ei saa steriloida uudelleen. Hävitä avatut, mutta käyttämättömät laitteet.
- Profylaktista antibioottilääkitystä voidaan antaa kirurgin normaalin käytännön mukaisesti.

KOMPLIKAATIOT

- Neulan sisäänviennin yhteydessä saattaa tapahtua kirurgista korjausta vaativia verisuonien, hermojen, virtsarakon tai suolen lävistyksiä tai repeämiä.
- Haava-alueella voi esiintyä tilapäistä paikallista ärsytystä sekä tilapäistä vierasainereaktiota. Tämä voi johtaa laitteen poistumiseen kehosta, eroosioon, fistelin muodostumiseen tai tulehdukseen.
- Kuten kaikki vierasaineet, PROLENE-verkko voi pahentaa olemassa olevaa infektiota. PROLENE-verkkoa sisäänventilivaiheessa suojaava muovisuojus vähentää kontaminoitumisen vaaraa.
- Ylikorjaus, toisin sanoen nauhan kiristäminen liian kireälle, voi aiheuttaa tilapäistä tai pysyvää alempien virtsateiden tukkeutumista.

VAIKUTUKSET

Eläinkokeissa on osoitettu, että PROLENE-verkko aiheuttaa kudoksessa vain erittäin vähäisen, tilapäisen tulehdusreaktion, jota seuraa ohuen verkon silmien läpikasvavan sidekudoskerroksen muodostuminen, mikä kiinnittää verkon ympäröivään kudokseen. Materiaali ei resorboidu, eikä se myöskään hajoa tai heikkene kudossyömyiden vaikutuksesta.

TOIMITUSTAPA

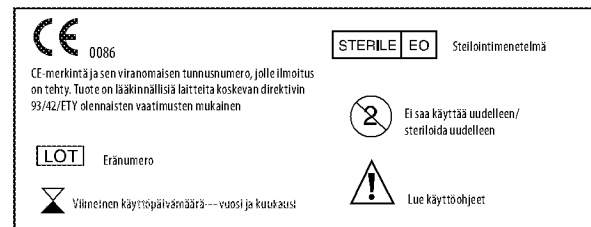
GYNECARE TVT -obturaattorijärjestelmä toimitetaan steriilinä (etyleenioksidi) kertakäyttöön. Ei saa steriloida uudelleen. Tämän laitteen (tai laitteen osien) uudelleenkäyttäminen voi aiheuttaa tuotteen haurastumisen ja likaantumisen, mikä voi johtaa infektiin tai veren mukana kulkeutuvien patogeenien siirtymisen potilaaseen ja käyttäjään. Ei saa käyttää, jos pakkaus on avattu tai vaurioitunut. Hävitä avatut, käyttämättömät laitteet.

SÄILYTYS

Kertakäyttöistä GYNECARE TVT -obturaattorijärjestelmää on säilytettävä alle 25 °C:n lämpötilassa suojattuna kosteudelta ja lämmöltä. Ei saa käyttää viimeisen käyttöpäivän jälkeen.

HUOMIO: Yhdysvaltain liittovaltion lain mukaan tämän tuotteen saa myydä ainoastaan lääkäri tai lääkärin määräyksestä.

MERKITSEMISESSÄ KÄYTETTÄVÄT SYMBOLIT



FRANÇAIS

Système obturateur **GYNECARE TVT™**
Dispositif sans tension contre les incontinences

Obturateur GYNECARE TVT, usage unique stérile

**Spirales de mise en place pour obturateur
GYNECARE TVT, usage unique stérile**

**Guide atraumatique à ailettes pour obturateur
GYNECARE TVT, usage unique stérile**

Lire attentivement toutes les informations.

Toute inobservation de ces instructions pourrait entraîner un fonctionnement incorrect du dispositif et provoquer des blessures.

Important :

Cette notice constitue le mode d'emploi du système obturateur GYNECARE TVT™, y compris le dispositif obturateur, les spirales de mise en place et le guide atraumatique à ailettes GYNECARE TVT. Il ne s'agit pas d'un document de référence complet en matière de technique chirurgicale pour remédier aux problèmes d'incontinences urinaires à l'effort. Ce dispositif doit être utilisé uniquement par des médecins formés au traitement chirurgical des incontinences urinaires à l'effort et tout spécialement à l'implantation du dispositif obturateur GYNECARE TVT. Ces instructions sont conçues pour un usage général du dispositif. L'utilisation du dispositif peut être modifiée pour répondre à des variantes personnelles de la technique opératoire et à des variations anatomiques de la patiente.

DESCRIPTION

Le système obturateur GYNECARE TVT est une trousse d'intervention stérile à usage unique destinée à une seule patiente, et comporte les éléments suivants :

Obturateur GYNECARE TVT

L'obturateur GYNECARE TVT est un dispositif stérile, destiné à une seule patiente, et composé d'un morceau de bande en polypropylène PROLENE™ non teintée ou bleue (bleu de phthalocyanine, numéro d'indice de coloration 74160) d'environ 1,1 cm x 45 cm, recouverte d'une gaine en plastique en son centre. Des logements de tube en plastique sont fixés à chaque extrémité. La maille en polypropylène PROLENE est constituée de filaments entrelacés de brins de polypropylène extrudé dont la composition est identique à celle des sutures chirurgicales non résorbables PROLENE en polypropylène. Lorsqu'il est utilisé pour des sutures, ce matériau s'est avéré inerte et indéformable en usage clinique. La maille PROLENE est obtenue au moyen d'un procédé qui entrelace chaque jonction de fibres et qui permet d'obtenir une élasticité dans les deux directions. Cette propriété offre une adaptation aux contraintes de l'organisme.

Spirales GYNECARE TVT

Les spirales GYNECARE TVT sont deux dispositifs en acier inoxydable munis d'une poignée en plastique et conçus pour mettre en place l'obturateur GYNECARE TVT. Le coffret comprend une spirale droite et une spirale gauche qui sont déjà montées sur l'obturateur GYNECARE TVT. Elles ne DOIVENT en aucun cas être courbées ni déformées.

Guide atraumatique à ailettes GYNECARE TVT

Le guide atraumatique à ailettes GYNECARE TVT est un accessoire en acier inoxydable qui facilite le passage des spirales GYNECARE TVT dans le passage disséqué.

INDICATIONS

L'obturateur GYNECARE TVT est conçu pour être utilisé sur des patientes comme bandelette sous-urétrale pour le traitement de l'incontinence urinaire à l'effort provenant d'une hypermobilité urétrale et/ou d'une déficience sphinctérienne intrinsèque.

MODE D'EMPLOI

(Remarque : la position des mains sur les illustrations peut varier.)

1. Placer la patiente en position gynécologique dorsale avec les hanches hyperfléchies au-dessus de l'abdomen. Les fesses doivent arriver au niveau du bord de la table.
2. L'intervention peut être effectuée sous anesthésie locale, régionale ou générale.
3. Le cas échéant, écarter les lèvres pour une meilleure exposition.
4. Insérer un cathéter urétral dans la vessie pour la vider.
5. Pour marquer les points de sortie des tubes en plastique, tracer une ligne horizontale au niveau du méat urétral, et une deuxième ligne parallèle à la première, deux centimètres au-dessus. Placer ensuite les deux points de sortie sur cette ligne, deux centimètres à côté du pli de la cuisse (aplanir éventuellement la peau en l'étirant). Marquer les points de sortie ; il est également possible de pratiquer une incision de 5 mm à 10 mm au niveau de chaque point de sortie ou plus tard lors de l'intervention (cf. figure 1).

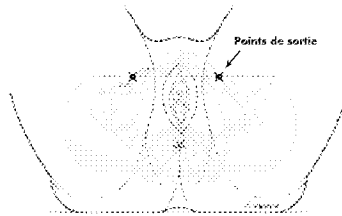


FIGURE 1

6. Au moyen d'une pince d'Allis pour la traction, pratiquer une incision médiane d'un centimètre dans la muqueuse vaginale en commençant à un centimètre du méat urétral.

(Remarque : il est conseillé de terminer l'insertion du dispositif d'un côté avant de commencer la dissection de l'autre côté.)

Après une première dissection à l'aide d'un instrument tranchant, poursuivre en utilisant la technique consistant à « pousser-écarter » afin de pratiquer une dissection par clivage, de préférence à l'aide de ciseaux courbes pointus. L'orientation de la dissection latérale doit former un angle de 45° par rapport à la ligne médiane, avec les ciseaux dirigés selon le plan horizontal (cf. figure 2). Continuer la dissection en direction de la « jonction » entre l'os du pubis et la branche pubienne inférieure (cf. figure 2).

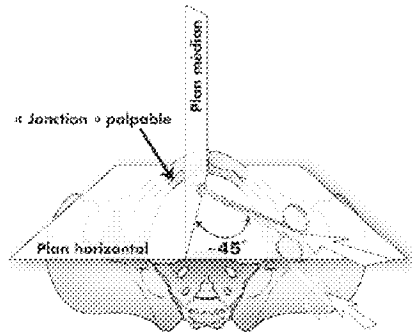


FIGURE 2

Lorsque la jonction entre l'os du pubis et la branche pubienne inférieure est atteinte, perforer la membrane de l'obturateur. Une perte de la résistance se fait sentir une fois la perforation effectuée. Le canal doit avoir un diamètre d'environ 5 mm à 7 mm et ne pas dépasser les 5 cm de profondeur. Toute dissection au-delà de 5 cm pourrait entraîner une pénétration involontaire dans l'espace de Retzius. Si l'on n'atteint pas l'os après une dissection de 5 cm, il convient alors de revérifier si l'angle de dissection est correct.

7. Retirer la station de travail interne de l'emballage externe. Puis, retirer le guide à ailettes GYNECARE TVT de la station de travail (cf. figure 3).

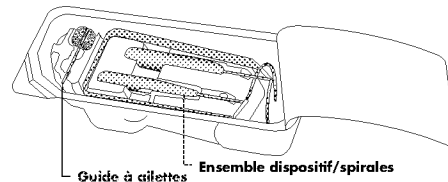


FIGURE 3

8. Insérer le guide à ailettes GYNECARE TVT dans le passage disséqué jusqu'à ce qu'il dépasse la branche pubienne inférieure et entre dans l'ouverture pratiquée précédemment dans la membrane de l'obturateur. Une disparition de la résistance est sensible lorsque le guide à ailettes passe à travers la membrane de l'obturateur.

Si une difficulté survient lors de l'insertion du guide, revérifier la direction du passage avec les ciseaux.

(Remarque : le côté ouvert du guide doit être dirigé vers le chirurgien. Le cas échéant, la languette flexible peut être repliée pour augmenter la longueur du guide, cf. figure 5.)

9. Retirer l'ensemble dispositif/spirales GYNECARE TVT et l'obturateur GYNECARE TVT de l'emballage stérile (cf. figure 3 pour les composants).

(Remarque : pour garantir une orientation correcte de la bande et des spirales, vérifier si le logo GYNECARE et la place du pouce sur les poignées en plastique sont bien dirigés vers le chirurgien, et si les pointes sont tournées vers l'extérieur, en direction du chirurgien. La spirale se trouvant dans la main gauche du chirurgien correspond au côté droit de la patiente, cf. figure 4.)

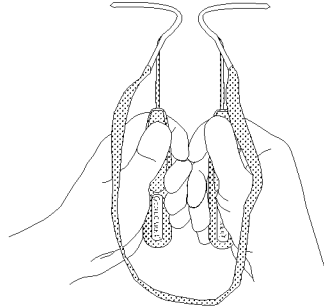


FIGURE 4

10. Placer l'une des spirales sur le champ stérile ou tout autre emplacement stérile approprié jusqu'au moment de s'en servir. S'assurer que la bandelette n'est pas tordue.
11. Insérer la spirale GYNECARE TVT correcte dans le passage disséqué en suivant le canal du guide à ailettes GYNECARE TVT. Pousser le dispositif vers l'intérieur pour traverser et dépasser légèrement la membrane de l'obturateur. Vérifier si la poignée du dispositif est orientée de manière à ce que l'extrémité droite de la spirale soit alignée sur le canal du guide à ailettes GYNECARE TVT et reste dirigée ainsi jusqu'à ce qu'elle traverse la membrane de l'obturateur (cf. figure 5).

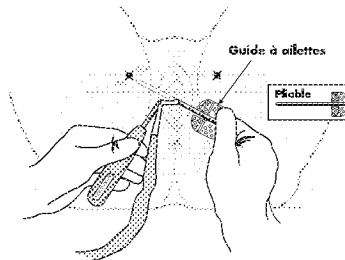


FIGURE 5

12. Une fois dans cette position, retirer le guide à ailettes GYNECARE TVT et le conserver stérile pour un usage ultérieur sur la même patiente.

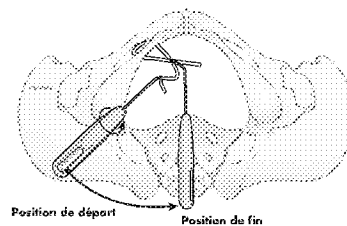


FIGURE 6

13. Une fois le guide à ailettes GYNECARE TVT retiré, faire pivoter la poignée de la spirale tout en la faisant progresser vers la ligne médiane jusqu'à ce qu'elle soit à la verticale par rapport au sol (cf. figure 6). *(Remarque : la poignée ne doit jamais être dirigée en position horizontale.)*

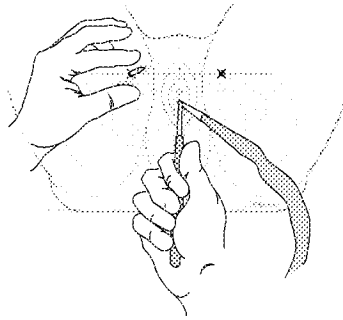


FIGURE 7

14. La pointe de la spirale doit sortir près du point de sortie déterminé auparavant (cf. figure 7). Cependant, une petite manipulation cutanée peut s'avérer nécessaire. Si l'incision cutanée n'a pas déjà été effectuée, elle doit être pratiquée au point où l'extrémité de la spirale apparaît sous la peau. Lorsque l'extrémité du tube en plastique apparaît au niveau de l'incision, saisir l'extrémité pointue du tube en plastique au moyen d'une pince et, tout en maintenant avec le pouce le tube immobile au niveau de l'urètre, retirer la spirale avec une rotation en sens inverse de la poignée (cf. figure 8).

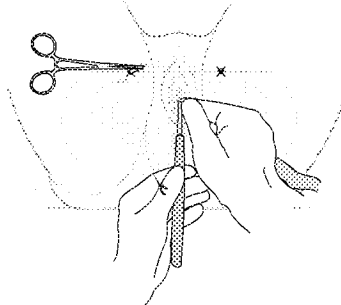


FIGURE 8

15. Tirer entièrement le tube en plastique à travers la peau jusqu'à l'apparition de la bandelette (cf. figure 9).

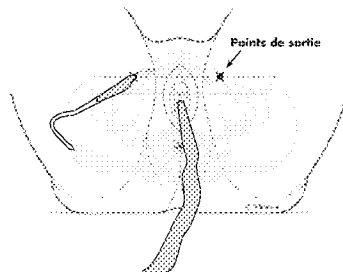


FIGURE 9

16. Procéder de même pour l'autre côté de la patiente et s'assurer que la bandelette repose à plat sous l'urètre (cf. figure 10).

(Remarque : si une torsion est présente dans la bandelette, s'assurer qu'elle ne se retrouve pas placée sous l'urètre après avoir tiré l'excédent de bandelette.)

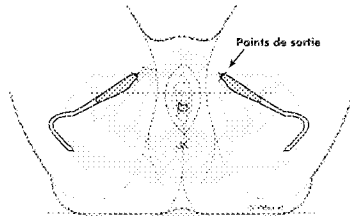


FIGURE 10

17. Lorsque les deux tubes en plastique sont sortis par les incisions cutanées, couper ces tubes de la bandelette et des gaines en plastique. Placer la bandelette à plat, sans la tendre, sous le milieu de l'urètre. Procéder à un test de toux afin de pouvoir tendre la bandelette de manière à obtenir seulement une perte de quelques gouttes d'urine lors de la toux (cf. figure 11).

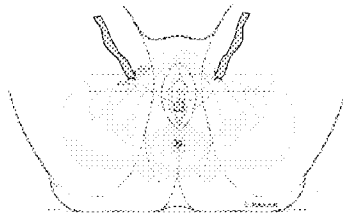


FIGURE 11

Une fois la bandelette en place, retirer la gaine en plastique qui la recouvre. Pour éviter de mettre la bandelette sous tension, placer un instrument moussé (par exemple des ciseaux ou des forceps) entre l'urètre et la bandelette lors du retrait des gaines en plastique, ou utiliser tout autre moyen approprié lors du retrait des gaines.

(Remarque : un retrait prématuré de la gaine peut entraîner des problèmes d'ajustement ultérieurs.)

18. Après avoir ajusté la bandelette, refermer l'incision vaginale. Couper les extrémités de la bandelette aux points de sortie, juste sous la peau de la partie interne des cuisses. Fermer les incisions cutanées au moyen de points de suture ou d'adhésif cutané chirurgical.
19. Le chirurgien peut choisir de procéder à une cystoscopie. Si une cystoscopie a déjà été effectuée après le premier passage, s'assurer que la vessie est vide avant de commencer le passage du second côté. Suite à l'opération, il n'est en général pas nécessaire de laisser de sonde à demeure. Prévoir d'inviter la patiente à vider sa vessie 2 ou 3 heures après l'opération.

CONTRE-INDICATIONS

Comme tout type d'intervention de soutènement, cette procédure ne doit pas être utilisée chez la femme enceinte. De plus, la bandelette PROLENE n'est pas suffisamment élastique pour être utilisée chez la patiente susceptible d'être enceinte ou dont la croissance n'est pas terminée.

MISES EN GARDE ET PRÉCAUTIONS D'EMPLOI

- La mise en place d'un obturateur GYNECARE TVT ne doit pas être effectuée sur des patientes sous anticoagulants.
- Ne pas utiliser d'obturateur GYNECARE TVT chez une femme présentant une infection du tractus urinaire.
- Avant d'employer l'obturateur GYNECARE TVT, les utilisateurs doivent connaître les techniques chirurgicales de soutènement urétral et avoir reçu une formation appropriée pour l'usage de ce dispositif.
- Il est impératif de respecter les bonnes pratiques chirurgicales pour la mise en place de l'obturateur GYNECARE TVT ainsi que pour le traitement des plaies contaminées ou infectées.
- La procédure relative à l'obturateur GYNECARE TVT doit être observée avec précaution afin d'éviter les gros vaisseaux, les nerfs, la vessie et l'intestin. Les risques seront minimisés si le chirurgien tient compte de l'anatomie de la patiente et procède avec précaution pour le passage du dispositif.
- Une hémorragie post-opératoire est possible. Il convient d'en rechercher les symptômes et les signes avant d'autoriser la sortie de la patiente de l'hôpital.
- Même si une lésion de la vessie est peu probable avec l'emploi de cette technique, le chirurgien peut choisir de procéder à des cystoscopies.
- Ne pas retirer les gaines en plastique tant que la bandelette n'a pas été correctement positionnée.
- S'assurer que la bandelette est placée sans tension sous la zone mi-urétrale.
- Ne pas procéder à cette intervention s'il est possible que le site chirurgical soit infecté ou contaminé.

- Comme aucune information clinique n'est disponible sur les femmes enceintes suite à la pose d'une bandelette sous-urétrale au moyen du système obturateur GYNECARE TVT, il convient d'informer la patiente que toute grossesse ultérieure risque d'annuler les effets de l'intervention chirurgicale, auquel cas le problème d'incontinence pourrait réapparaître.
- Comme aucune information clinique n'est disponible sur l'accouchement par voie basse suite à la pose d'une bandelette sous-urétrale au moyen du système obturateur GYNECARE TVT, il convient de prévoir une césarienne en cas de grossesse.
- Après l'opération, il doit être recommandé à la patiente d'éviter de soulever des objets lourds ou de s'adonner à des exercices trop contraignants (par ex., cyclisme, jogging) pendant au moins trois à quatre semaines. Les rapports sexuels sont aussi à éviter pendant un mois. La patiente peut normalement reprendre ses activités quotidiennes habituelles après une ou deux semaines.
- La patiente doit immédiatement prendre contact avec le chirurgien en cas de dysurie, de saignements ou de tout autre problème.
- Des douleurs passagères dans les jambes pendant 24 à 48 heures sont possibles et peuvent normalement être traitées avec de faibles doses d'analgésiques.
- Comme avec d'autres interventions visant à remédier aux incontinences, une instabilité de novo du detrusor peut se produire suite à la pose d'une bandelette sous-urétrale au moyen du système obturateur GYNECARE TVT. Pour minimiser ce risque, s'assurer de placer la bandelette comme indiqué ci-dessus.
- Ne pas placer la bandelette de PROLENE au contact d'agrafes, de clips ou de clamps qui seraient susceptibles de la détériorer.
- Ne pas restériliser l'obturateur GYNECARE TVT ni ses composants. Jeter les dispositifs non utilisés dont l'emballage a été ouvert.
- Des antibiotiques prophylactiques peuvent être prescrits selon les habitudes du chirurgien.

RÉACTIONS INDÉSIRABLES

- Des perforations ou des lacerations de vaisseaux, de nerfs, de la vessie ou de l'intestin peuvent se produire lors du passage de l'aiguille et entraîner la nécessité d'une réparation chirurgicale.
- Une irritation transitoire au niveau du site de la plaie et une réaction provisoire aux corps étrangers peuvent apparaître. Cette réponse peut se traduire par une extrusion, une érosion, la formation de fistules ou une inflammation.
- Comme tous les corps étrangers, la bandelette de PROLENE est susceptible d'activer une infection existante. Les gaines en plastique qui couvrent initialement la bandelette de PROLENE sont conçues pour minimiser les risques de contamination.
- Une correction excessive, c'est-à-dire une trop grande tension de la bandelette, peut causer une obstruction temporaire ou permanente du tractus urinaire inférieur.

PERFORMANCES

Les études sur animaux ont démontré que la mise en place d'une bandelette de PROLENE provoque une réaction inflammatoire tissulaire minime transitoire suivie du dépôt d'une couche fibreuse tissulaire mince qui peut pénétrer à travers les interstices de la bandelette et l'incorporer ainsi au tissu adjacent. Le matériau n'est pas résorbé ou dégradé ni fragilisé par l'action des enzymes tissulaires.

PRÉSENTATION

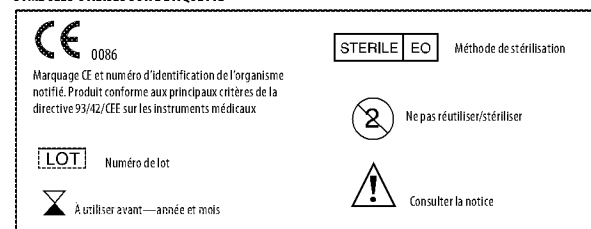
Le système obturateur GYNECARE TVT à usage unique est fourni stérile (stérilisation à l'oxyde d'éthylène). Ne pas restériliser. La réutilisation de ce dispositif (ou de parties de ce dispositif) peut créer un risque de dégradation du produit et une contamination croisée, ce qui peut provoquer une infection ou la transmission d'agents pathogènes transmissibles par le sang aux patients et utilisateurs. Ne pas utiliser si l'emballage est ouvert ou détérioré. Jeter les dispositifs non utilisés dont l'emballage a été ouvert.

STOCKAGE

Il est recommandé de stocker le système obturateur GYNECARE TVT à usage unique à une température inférieure à 25 °C, à l'abri de l'humidité et de la chaleur directe. Ne pas utiliser au-delà de la date de péremption.

ATTENTION : en vertu de la loi fédérale des États-Unis, ce dispositif ne peut être vendu que par un médecin ou sur ordonnance médicale.

SYMBOLES UTILISÉS SUR L'ÉTIQUETTE



DEUTSCH**GYNECARE TVT™ Obturatorsystem
Spannungsfreie Unterstützung bei Inkontinenz****GYNECARE TVT Obturator-Implantat,
steril, zum Einmalgebrauch****GYNECARE TVT Obturator-Applikatoren,
steril, zum Einmalgebrauch****Atraumatische Flügelsonde für GYNECARE TVT Obturator,
steril, zum Einmalgebrauch****Bitte alle Informationen sorgfältig durchlesen.**

Wenn die Anweisungen nicht korrekt befolgt werden, kann dies zu Fehlfunktionen des Systems und zu Verletzungen führen.

Wichtig:

Diese Packungsbeilage enthält die Gebrauchsanweisung für das GYNECARE TVT™ Obturatorsystem, einschließlich GYNECARE TVT Obturator-Implantat, Applikatoren und atraumatischer Flügelsonde. Sie darf nicht als umfassendes Handbuch der chirurgischen Technik zur Behandlung der SHI (Stress-Harninkontinenz) angesehen werden. Das Produkt sollte nur von Ärzten verwendet werden, die Erfahrung in der chirurgischen Behandlung einer Stress-Harninkontinenz und insbesondere der Implantation des GYNECARE TVT Obturator-Implantats haben. Diese Anweisungen beziehen sich auf die allgemeine Verwendung des Produkts. Abweichungen in der Anwendung können sich infolge individueller Operationsmethoden oder der Anatomie der Patientin ergeben.

BESCHREIBUNG

Das GYNECARE TVT Obturatorsystem ist ein steriles Kit zum Einmalgebrauch und besteht aus:

GYNECARE TVT Obturator-Implantat

Das GYNECARE TVT Obturator-Implantat ist ein steriles Produkt zur einmaligen Anwendung, das aus einem ungefärbten oder blauen (Phthalocyaninblau, Farbindexnummer 74160) PROLENE™ Polypropylen-Netz (Streifen) besteht, das ca. 1,1 cm x 45 cm misst und von einem Plastikschutz umgeben ist, der sich in der Mitte des Streifens überlappt. An jedem Ende ist eine röhrenförmige Kunststoffhülse befestigt. Das PROLENE Polypropylen-Netz besteht aus verknüpften Fasern von extrudierten Polypropylensträngen, die denen des PROLENE nicht resorbierbaren, chirurgischen Polypropylen-Nahtmaterials entsprechen. Es wurde berichtet, dass dieses Material bei Verwendung als chirurgisches Nahtmaterial keinerlei Reaktionen hervorruft und seine Festigkeit bei klinischer Anwendung unbeschränkt erhalten bleibt. Das PROLENE-Netz ist so verknüpft, dass die Faserverbindungen miteinander verkettet sind, wodurch es bidirektional dehnbar ist. Diese bidirektionale Elastizität ermöglicht die Adaptation an verschiedene Belastungssituationen im Körper.

GYNECARE TVT Obturator-Applikatoren

Die GYNECARE TVT Applikatoren sind zwei gebogene Edelstahl-Nadeln mit Kunststoffgriffen zur Einführung des GYNECARE TVT Obturator-Implantats. Die Applikatoren werden paarweise als rechtes und linkes Instrument und am GYNECARE TVT Obturator-Implantat vormontiert geliefert. Die Einführungsspirale DARF KEINESFALLS in irgendeiner Weise gebogen oder verformt werden.

Atraumatische Flügelsonde für GYNECARE TVT Obturator

Die GYNECARE TVT atraumatische Flügelsonde ist ein Hilfsinstrument aus Edelstahl, das die Passage der GYNECARE TVT Applikatoren durch den Schnitt erleichtert.

INDIKATIONEN

Das GYNECARE TVT Obturator-Implantat wird als suburethrale Schlinge bei Frauen zur Behandlung von Stress-Harninkontinenz (SHI) verwendet, die durch eine Hypermobilität der Urethra und/oder eine intrinsische Sphinkterinsuffizienz bedingt ist.

GEBRAUCHSANWEISUNG

(Hinweis: Die in den Abbildungen gezeigten Handpositionen können variieren.)

1. Die Patientin in der dorsalen Steinschnittlage mit über den Bauch hyperflexierten Hüften positionieren. Die Gesäßbacken sollten bündig mit der Tischkante positioniert werden.
2. Der Eingriff kann in Lokal-, Regional- oder Allgemeinanästhesie durchgeführt werden.
3. Falls gewünscht, die Labia zurückziehen, um zusätzliche Fläche freizulegen.
4. Einen Harnröhrenkatheter in die Blase schieben und die Blase entleeren.

5. Die Austrittspunkte der Kunststoffröhrchen durch eine horizontale Linie auf Höhe der Harnröhrenöffnung und eine zweite Linie, die parallel im Abstand von 2 cm oberhalb der ersten Linie verläuft, markieren. Die Austrittspunkte auf dieser Linie 2 cm lateral der Hüftbeugefalte lokalisieren (die Haut lässt sich durch Ziehen glätten). Die Austrittspunkte markieren; alternativ kann eine 5 mm–10 mm lange Inzision an beiden Punkten sofort oder erst in einer späteren Phase des Eingriffs gemacht werden (siehe Abbildung 1).

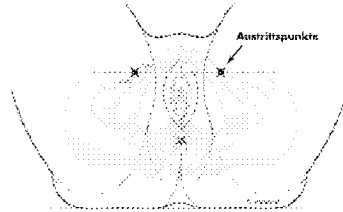


ABBILDUNG 1

6. Unter Zuganwendung mit Allis-Klemmen eine 1 cm lange Mittellinien-Inzision in der Vaginalmukosa machen, ab 1 cm proximal der Harnröhrenöffnung.

(Hinweis: Es wird empfohlen, die Insertion des Implantats auf einer Seite abzuschließen, bevor auf der anderen Seite inzidiert wird.)

Nachdem mit einer scharfen Dissektion begonnen wurde, mittels Schub-Spreiz-Technik fortfahren, um eine stumpfe Dissektion vorzunehmen, vorzugsweise mit einer spitzen, gebogenen Schere. Der Pfad für die laterale Dissektion sollte im Winkel von 45° zur Mittellinie verlaufen, wobei die Schere horizontal ausgerichtet ist (siehe Abbildung 2). Mit der Dissektion in Richtung Kreuzungspunkt zwischen dem Schambeinkörper und dem unteren Ast des Schambeins fortfahren (siehe Abbildung 2).

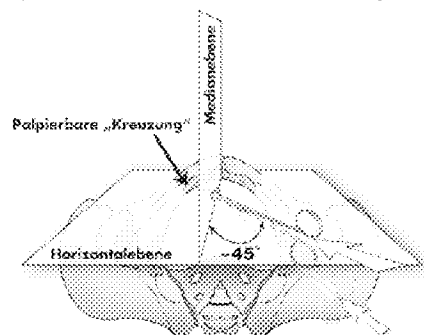


ABBILDUNG 2

Wenn der Kreuzungspunkt zwischen Schambein und inferiorem Ramus pubis erreicht wurde, die Obturatormembran perforieren. Wenn die Membran perforiert ist, lässt sich ein verringerter Widerstand fühlen. Der Kanal sollte einen Durchmesser von 5 mm bis 7 mm haben und nicht tiefer als 5 cm sein. Eine Präparation über 5 cm hinaus kann zur unbeabsichtigten Eröffnung des Retzius-Raums führen. Wenn nach 5 cm Präparation der Knochen nicht erreicht wird, nochmals überprüfen, ob der Präparationswinkel korrekt ist.

7. Den gesamten Paketinhalt aus der äußeren Verpackung nehmen. Anschließend die GYNECARE TVT Führungshilfe aus dem Paket entnehmen (siehe Abbildung 3).

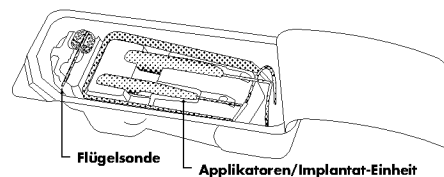


ABBILDUNG 3

8. Die GYNECARE TVT Flügelsonde in den präparierten Gang schieben, bis sie den unteren Ramus des Schambeins passiert und in die zuvor angelegte Öffnung der Obturatormembran gelangt. Der fehlende Widerstand, wenn die Flügelsonde durch die Obturatormembran geht, ist spürbar.

Wenn beim Einschieben der Sonde Schwierigkeiten auftreten, nochmals die Richtung des Gangs mit der Schere bestätigen.

(Hinweis: Die offene Seite der Sonde muss zum Operateur zeigen. Die biegsame Platte kann umgebogen werden, um die Sonde bei Bedarf zu verlängern, siehe Abbildung 5.)

9. Die GYNECARE TVT Applikatoren und das GYNECARE TVT Obturator-Implantat aus der sterilen Verpackung nehmen (Komponenten siehe Abbildung 3).

(Hinweis: Um die korrekte Orientierung der Applikatoren und des Implantats zu gewährleisten, müssen das GYNECARE Logo und die Daumenvertiefung am Kunststoffgriff zum Operateur und die Spitzen nach außen zeigen. Der Applikator in der linken Hand des Operateurs muss auf der rechten Seite der Patientin verwendet werden; siehe Abbildung 4.)

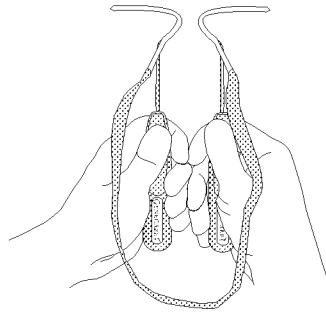


ABBILDUNG 4

10. Einen der Applikatoren auf das sterile Tuch oder an einen anderen sterilen Ort legen, bis er gebraucht wird. Das Implantat darf dabei nicht verdreht sein.
11. Den richtigen GYNECARE TVT Applikator in den präparierten Gang schieben und dabei dem Kanal der GYNECARE TVT Flügelsonde folgen. Das Instrument nach innen drücken, wobei die Obturatormembran durchquert und passiert wird. Dabei muss der Griff so orientiert sein, dass die gerade Spitze der Einführungsspirale entsprechend dem Kanal in der GYNECARE TVT Flügelsonde ausgerichtet ist und in dieser Stellung bleibt, bis die Spitze die Obturatormembran durchquert (siehe Abbildung 5).

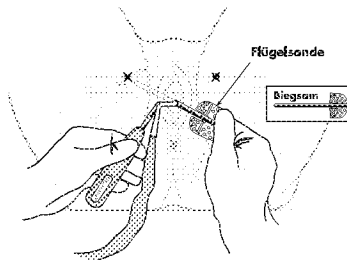


ABBILDUNG 5

12. Wenn diese Position erreicht ist, die GYNECARE TVT Flügelsonde entfernen und für die spätere nochmalige Verwendung bei der gleichen Patientin steril halten.

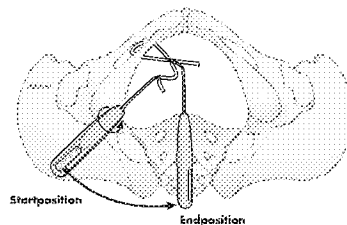


ABBILDUNG 6

13. Nachdem die GYNECARE TVT Führungshilfe entnommen wurde, den Griff des Applikators drehen, dabei gleichzeitig in Richtung Mittellinie bewegen, bis sich der Griff in vertikaler Position zum Boden befindet (siehe Abbildung 6). **(Hinweis: Den Griff niemals in die Horizontale ausrichten.)**

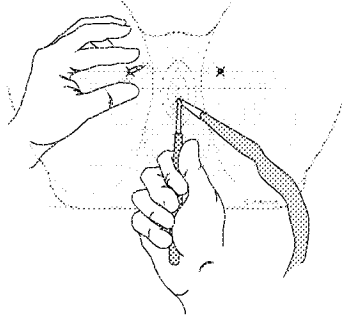


ABBILDUNG 7

14. Die Spitze des Applikators sollte in der Nähe des zuvor bestimmten Austrittspunkts austreten (siehe Abbildung 7). Es kann jedoch eine geringfügige Hautmanipulation erforderlich sein. Falls die Hautinzision nicht bereits vorgenommen wurde, die Inzision an der Stelle vornehmen, an der die Spitze des Applikators unter der Haut zum Vorschein kommt. Wenn die Spitze des Plastikschräuchs an der Hautöffnung erscheint, das spitz zulaufende Ende des Plastikschräuchs mit einer Klammer greifen und, während der Schlauch in der Nähe der Harnröhre mit dem Daumen stabilisiert wird, den Applikator durch eine Gegendrehung des Griffs entfernen (siehe Abbildung 8).

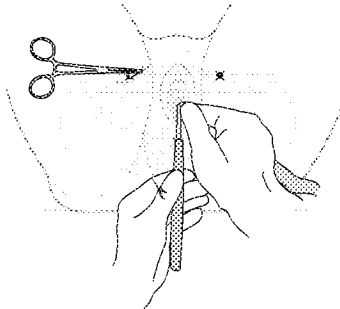


ABBILDUNG 8

15. Das Kunststoffröhrchen vollständig durch die Haut ziehen, bis der Streifen erscheint (siehe Abbildung 9).

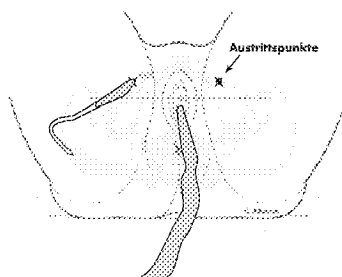


ABBILDUNG 9

16. Das Verfahren auf der anderen Seite der Patientin wiederholen, dabei muss das Implantat flach unter der Harnröhre liegen (siehe Abbildung 10).
(Hinweis: Wenn eine Verdrehung des Implantats entdeckt wird, darf sich die Verdrehung nicht unter der Harnröhre befinden, wenn der restliche Streifen durchgezogen ist.)

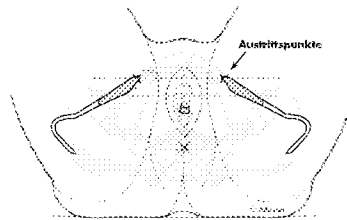


ABBILDUNG 10

17. Wenn beide Kunststoffröhrchen durch die Hautinzisionen gezogen sind, die Kunststoffröhrchen vom Streifen und dem Plastikschutz abschneiden. Den Streifen lose, d.h. ohne Zugspannung, und flach unter der Harnröhrenmitte positionieren. An diesem Punkt kann ein Hustentest durchgeführt werden. Dieser ermöglicht die Anpassung des Streifens, so dass beim Husten nur wenige Tropfen Urin abgehen (siehe Abbildung 11).

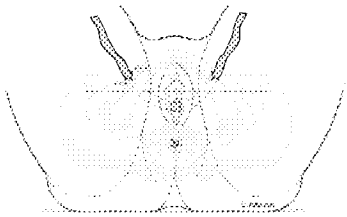


ABBILDUNG 11

Wenn das Implantat korrekt positioniert ist, die Plastikhülle entfernen, die den Streifen abdeckt. Beim Entfernen der Plastikummüllungen ein stumpfes Instrument (z.B. Schere, Pinzette oder ähnliches) zwischen Harnröhre und Streifen positionieren, damit der Streifen nicht unter Zugspannung steht.

(Hinweis: Ein vorzeitiges Entfernen der Schutzhülle kann nachfolgende Anpassungen erschweren.)

18. Nach Anpassung des Implantats die vaginale Inzision verschließen. Die Streifenenden an den Austrittspunkten direkt unter der Haut abschneiden. Die Hautinzisionen mit einer Naht oder chirurgischem Hautkleber verschließen.
19. Nach Ermessen des Arztes kann eine Zystoskopie durchgeführt werden. Wenn im Anschluss an die erste Passage eine Zystoskopie durchgeführt wurde, muss die Blase entleert werden, bevor mit der Passage der zweiten Seite begonnen wird. Nach diesem Eingriff ist eine postoperative Katheterisierung im Allgemeinen nicht nötig. Die Patientin sollte 2–3 Stunden nach Operationsende zur Entleerung der Blase aufgefordert werden.

KONTRAINDIKATIONEN

Wie bei jeder Suspensionsoperation sollte dieses Verfahren nicht bei Patientinnen mit bestehender Schwangerschaft durchgeführt werden. Bei der Verwendung des PROLENE Polypropylen-Netzes im wachsenden Organismus sollte bedacht werden, dass das Netz sich trotz seiner Flexibilität nicht dem Wachstum entsprechend dehnen kann. Dieses ist auch bei Patientinnen mit geplanter oder zukünftig gewünschter Schwangerschaft zu beachten.

WARNHINWEISE UND VORSICHTSMASSNAHMEN

- Das GYNECARE TVT Obturatorsystem nicht bei Patientinnen verwenden, die gerinnungshemmende Medikamente einnehmen.
- Das GYNECARE TVT Obturatorsystem nicht bei Patientinnen mit Harnwegsinfektionen verwenden.
- Die Anwender sollten mit der chirurgischen Technik für urethrale Suspensionen vertraut und entsprechend für das GYNECARE TVT Obturatorsystem ausgebildet sein, bevor sie ein GYNECARE TVT Obturator-Implantat einsetzen.
- Sowohl beim GYNECARE TVT Obturatorsystem als auch bei der Versorgung von kontaminierten oder infizierten Operationswunden sind die anerkannten chirurgischen Techniken anzuwenden.
- Das GYNECARE TVT Obturator-Verfahren sollte mit Sorgfalt durchgeführt werden, um eine Beschädigung größerer Blutgefäße sowie von Nerven, Blase und Darm zu vermeiden. Durch Beachtung der Anatomie der Patientin und die korrekte Passage des Geräts werden Risiken minimiert.
- Es können postoperative Blutungen auftreten. Auf diesbezügliche Symptome oder Anzeichen achten, bevor die Patientin aus dem Krankenhaus entlassen wird.
- Obwohl eine Verletzung der Blase bei dieser Technik unwahrscheinlich ist, kann nach ärztlichem Ermessen eine Zystoskopie durchgeführt werden.
- Plastikhülle nicht entfernen, bevor das Implantat korrekt platziert ist.
- Das Implantat muss unter minimaler Spannung unter dem mittleren Teil der Urethra platziert sein.

- Dieses Verfahren nicht durchführen, wenn Verdacht auf eine Infektion oder Kontamination des Operationsgebiets besteht.
- Da keine klinischen Informationen über eine Schwangerschaft nach suburethraler Umschlingung mit dem GYNECARE TVT Obturatorsystem vorliegen, sollte die Patientin dahingehend beraten werden, dass eine künftige Schwangerschaft die Wirkung des Eingriffs aufheben und die Inkontinenz erneut auftreten kann.
- Da keine klinischen Informationen über eine normale Entbindung nach suburethraler Umschlingung mit dem GYNECARE TVT Obturatorsystem vorliegen, sollte im Falle einer Schwangerschaft eine Entbindung durch Kaiserschnitt erwogen werden.
- Nach der Operation ist die Patientin darüber zu informieren, dass sie mindestens 3–4 Wochen kein schweres Heben bzw. keinen anstrengenden Sport (z.B. Radfahren, Jogging) betreiben sollte und dass Geschlechtsverkehr einen Monat lang vermieden werden sollte. Die Patientin kann für gewöhnlich nach einer Woche bis zwei Wochen alle anderen normalen Aktivitäten wieder ausführen.
- Bei Auftreten einer Dysurie, Blutung oder anderer Probleme sollte die Patientin sofort den Chirurgen benachrichtigen.
- Es können vorübergehende Schmerzen in den Beinen für 24–48 Stunden auftreten, die normalerweise mit leichten Analgetika zu behandeln sind.
- Wie bei anderen Inkontinenzbehandlungen kann eine erneute Instabilität des Entleerungsmuskels nach suburethraler Umschlingung mit dem GYNECARE TVT Obturatorsystem auftreten. Um dieses Risiko zu minimieren, muss der Streifen wie oben beschrieben platziert werden.
- Das PROLENE Netz darf nicht mit Klammern, Clips oder Klemmen in Kontakt kommen, da es dabei zu einer mechanischen Schädigung kommen kann.
- Das GYNECARE TVT Obturatorsystem oder seine Komponenten dürfen nicht erneut sterilisiert werden. Geöffnete, nicht verwendete Packungen entsorgen.
- Eine prophylaktische Verordnung von Antibiotika ist entsprechend der üblichen Verfahrensweise des Chirurgen möglich.

NEBENWIRKUNGEN

- Bei der Nadelpassage kann es zu Beschädigungen von Blutgefäßen, Nerven, Blase oder Darm in Form von Einstichen oder Rissen kommen, die chirurgischer Reparatur bedürfen.
- Es kann vorübergehend zu einer lokalen Irritation der Wunde und einer Fremdkörperreaktion kommen. Dies kann zu einer Extrusion, Erosion, Fistelbildung oder Entzündung führen.
- Wie alle Fremdkörper kann das PROLENE Netz eine vorhandene Infektion negativ beeinflussen. Der Plastikschutz des PROLENE Netzes dient dazu, das Risiko einer Kontamination auf ein Minimum zu beschränken.
- Bei einer Überkorrektur, d.h. bei einer zu starken Spannung des Streifens, kann es zu einer vorübergehenden oder permanenten Stenose der unteren Harnwege kommen.

WIRKUNG

Tierstudien zeigen, dass die Implantation eines PROLENE Netzes eine vorübergehende minimale entzündliche Reaktion im Gewebe auslöst. Eine dünne Lage fibrösen Gewebes wächst dann durch die Zwischenräume des Netzes, wodurch das Netz in das umgebende Gewebe inkorporiert wird. Das Material wird weder resorbiert noch durch Gewebezynyme degradiert oder geschwächt.

LIEFERFORM

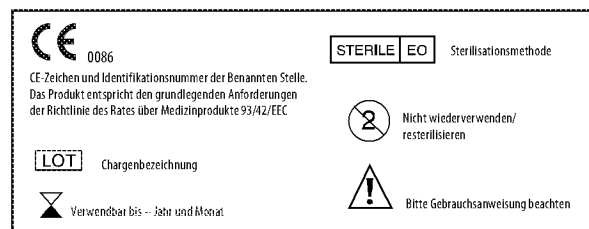
Das GYNECARE TVT Obturatorsystem wird steril (Ethylenoxid) zum Einmalgebrauch geliefert. Nicht erneut sterilisieren. Durch Wiederverwendung dieses Produkts (oder von Teilen dieses Produkts) besteht das Risiko einer Produktschädigung oder einer Kreuzkontamination, was zu einer Infektion oder Ansteckung mit durch Blut übertragenen Erregern bei Patienten und Anwendern führen kann. Nicht verwenden, wenn die Verpackung geöffnet oder beschädigt ist. Geöffnete, nicht verwendete Packungen entsorgen.

AUFBEWAHRUNG

Es wird empfohlen, das GYNECARE TVT Obturatorsystem bei Temperaturen unter 25 °C und geschützt vor Feuchtigkeit und direkter Hitzeeinwirkung aufzubewahren. Nach Ablauf des Verfalldatums nicht mehr verwenden.

ACHTUNG: Laut Gesetz in den USA darf dieses Produkt nur an Ärzte oder auf ärztliche Anordnung verkauft werden.

ERKLÄRUNG DER SYMBOLE AUF DER VERPACKUNG



ITALIANO**Sistema otturatorio GYNECARE TVT™
Dispositivo tension-free per l'incontinenza****Dispositivo otturatorio GYNECARE TVT
sterile, monouso****Tunnelizzatori otturatori elicoidali GYNECARE TVT
sterili, monouso****Guida otturatoria atraumatica con alette GYNECARE TVT
sterile, monouso****Leggere attentamente le istruzioni.**

Il mancato rispetto delle istruzioni può comportare un funzionamento errato del dispositivo con conseguente pericolo di lesioni.

Importante:

Questo inserto fornisce le istruzioni per l'uso del sistema otturatorio GYNECARE TVT™, compreso il dispositivo otturatorio, i tunnelizzatori otturatori elicoidali e la guida otturatoria atraumatica con alette GYNECARE TVT. Questo inserto non deve essere considerato una guida esauriente per la tecnica chirurgica di correzione dell'incontinenza urinaria da sforzo. Il dispositivo dovrebbe essere utilizzato solo da medici addestrati nel trattamento chirurgico dell'incontinenza urinaria da sforzo e, in particolare, nell'impianto del sistema otturatorio GYNECARE TVT. Queste istruzioni sono intese per l'uso generico del dispositivo. In procedure specifiche, l'uso del dispositivo può variare a seconda delle tecniche individuali e dell'anatomia della paziente.

DESCRIZIONE

Il sistema otturatorio GYNECARE TVT è un kit da procedura sterile, da usarsi su di una sola paziente, composto da:

Dispositivo otturatorio GYNECARE TVT

Il dispositivo otturatorio GYNECARE TVT è un prodotto sterile, da usarsi su di una sola paziente, composto da un nastro di maglia in polipropilene PROLENE™ non colorata o blu (blu di fialocianina, codice colore 74160) di circa 1,1 cm x 45 cm, ricoperto da una guaina in plastica, sovrapposta al centro. I tubi in plastica sono collegati a ciascuna estremità. Il nastro in polipropilene PROLENE è costituito da filamenti di polipropilene estruso intrecciati in una maglia, di composizione identica a quelli usati nelle suture chirurgiche non assorbibili in polipropilene PROLENE. Questo materiale, usato come sutura, è risultato non reattivo e, in applicazioni cliniche, ha dimostrato di mantenere la propria resistenza indefinitamente. Il nastro in PROLENE è lavorato con un processo che collega fra di loro ogni giunzione di fibra e che conferisce elasticità in entrambe le direzioni. Questa proprietà elastica bi-direzionale consente l'adattamento alle varie tensioni presenti nel corpo umano.

Tunnelizzatori otturatori elicoidali GYNECARE TVT

I tunnelizzatori otturatori elicoidali GYNECARE TVT consistono in due tunnelizzatori in acciaio inossidabile, a filo curvo con impugnature in plastica, progettati per utilizzare il dispositivo otturatorio GYNECARE TVT. I tunnelizzatori otturatori elicoidali sono forniti sia per sinistri che per destri e sono preassemblati al dispositivo otturatorio GYNECARE TVT. Il tunnelizzatore otturatorio elicoidale non DEVE mai essere piegato o deformato in alcun modo.

Guida otturatoria atraumatica con alette GYNECARE TVT

La guida otturatoria atraumatica con alette GYNECARE TVT è uno strumento accessorio in acciaio inossidabile che facilita il passaggio dei tunnelizzatori otturatori elicoidali GYNECARE TVT attraverso il tratto della dissezione.

INDICAZIONI

Il dispositivo otturatorio GYNECARE TVT è destinato ad essere usato nelle donne come sling sub-uretrale per il trattamento dell'incontinenza urinaria da sforzo (IUS) causata da una ipermobilità uretrale e/o da una insufficienza intrinseca dello sfintere.

ISTRUZIONI PER L'USO

(Nota: le posizioni delle mani mostrate nelle illustrazioni possono variare.)

1. Posizionare la paziente in posizione litotomica dorsale con le anche iperflesse sull'addome. Le natiche dovrebbero essere allineate al bordo del tavolo.
2. La procedura chirurgica è eseguita in anestesia locale, regionale o generale.
3. Se lo si desidera, ritrarre le labbra per fornire una esposizione aggiuntiva.
4. Inserire un catetere uretrale nella vescica e svuotarla.

5. Contrassegnare i punti di uscita dei tubi in plastica, tracciando una linea orizzontale al livello del meato uretrale, nonché una seconda linea parallela e posta 2 cm al di sopra della prima linea. Individuare i punti di uscita su questa linea, 2 cm lateralmente rispetto alle pieghe della coscia (è possibile appiattire la cute tirandola). Contrassegnare i punti di uscita, in alternativa è possibile eseguire un'incisione di 5 mm–10 mm in ciascun punto di uscita o in una fase successiva della procedura (osservare la figura 1).

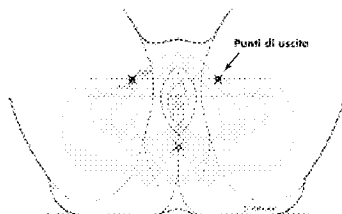


FIGURA 1

6. Con i morsetti Allis per la trazione, eseguire un'incisione a linea mediana di 1 cm nella mucosa vaginale, partendo da 1 cm prossimale al meato uretrale.

(Nota: si suggerisce di completare l'inserimento del dispositivo da un lato prima di iniziare la dissezione del secondo.)

Dopo aver dato inizio a una dissezione aguzza, continuare usando una tecnica di "pressione e spargimento", per eseguire la dissezione smussa preferibilmente facendo uso di forbici curve appuntite. È necessario orientare il percorso della dissezione laterale ad un angolo di 45° dalla linea mediana, con forbici orientate sul piano orizzontale (osservare la figura 2). Continuare la dissezione verso la congiunzione fra il corpo dell'osso pubico e il ramo pubico inferiore (osservare la figura 2).

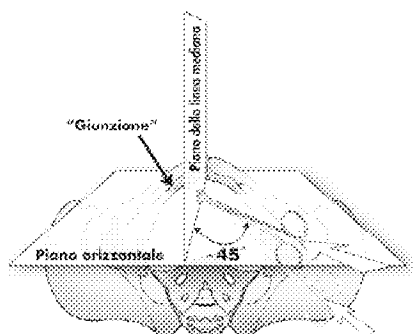


FIGURA 2

Quando si raggiunge la giunzione fra il corpo dell'osso pubico e il ramo pubico inferiore, perforare la membrana dell'otturatore. Quando la membrana viene perforata, è possibile avvertire una perdita di resistenza. Il canale deve avere un diametro di circa di 5–7 mm e non deve essere più profondo di 5 cm. Una dissezione oltre i 5 cm può causare un ingresso involontario nello spazio di Retzius. Dopo la dissezione di 5 cm, se non si raggiunge l'osso, valutare di nuovo che l'angolo di dissezione sia corretto.

7. Rimuovere la workstation con pacchetto interno dalla confezione esterna. Quindi rimuovere dalla confezione la guida otturatoria atraumatica con alette GYNECARE TVT (osservare la figura 3).

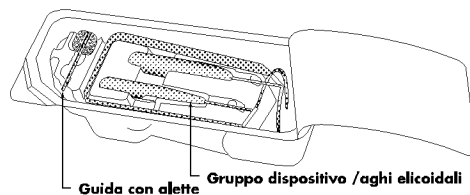


FIGURA 3

8. Inserire la guida otturatoria atraumatica con alette GYNECARE TVT nel tratto in cui è stata eseguita la dissezione, finché questa non oltrepassa il ramo pubico inferiore ed entra nell'apertura praticata precedentemente nella membrana dell'otturatore. Quando la guida con alette viene fatta passare attraverso la membrana dell'otturatore, è possibile avvertire una perdita di resistenza.

Se si avverte una certa difficoltà durante l'inserimento della guida, riconfermare la direzione del tratto con le forbici.

(Nota: il lato aperto della guida deve essere rivolto verso il chirurgo. Se necessario, è possibile piegare la linguetta pieghevole per aumentare la lunghezza della guida, osservare la figura 5.)

9. Rimuovere i tunnelizzatori otturatori elicoidali GYNECARE TVT ed il dispositivo otturatorio GYNECARE TVT dalla confezione sterile (per i componenti, osservare la figura 3).

(Nota: per garantire la giusta direzione dei tunnelizzatori otturatori elicoidali e del nastro, verificare che il logo GYNECARE ed il solco per pollice dell'impugnatura in plastica siano rivolti verso il chirurgo e i punti sulla parte esterna si trovino di fronte al chirurgo. È necessario che il chirurgo usi il tunnelizzatore otturatorio elicoidale con la mano sinistra, mentre opera sulla parte destra della paziente; osservare la figura 4.)

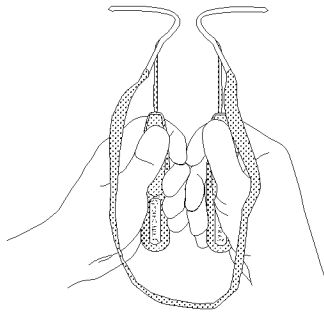


FIGURA 4

10. Posizionare uno dei tunnelizzatori otturatori elicoidali sul telo sterile o in altri luoghi sterili adatti, finché sarà necessario. Assicurarsi che il nastro non sia attorcigliato.
11. Inserire il tunnelizzatore otturatorio elicoidale GYNECARE TVT proprio nel tratto in cui è stata eseguita la dissezione, seguendo il canale della guida otturatoria atraumatica con alette GYNECARE TVT. Spingere il dispositivo all'interno, facendolo attraversare e passare leggermente oltre la membrana dell'otturatore. Accertarsi che l'impugnatura del dispositivo sia orientata in modo che la punta retta del tunnelizzatore otturatorio elicoidale sia allineata con il canale della guida otturatoria atraumatica con alette GYNECARE TVT e rimanga in quella direzione finché la punta non attraversa la membrana dell'otturatore (osservare la figura 5).

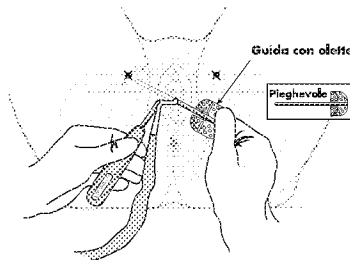


FIGURA 5

12. Una volta raggiunta questa posizione, rimuovere la guida otturatoria atraumatica con alette GYNECARE TVT e mantenerla sterile per un uso successivo sulla stessa paziente.

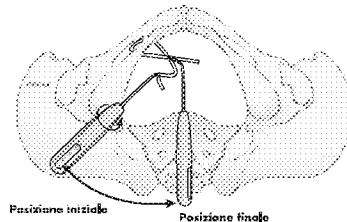


FIGURA 6

13. Una volta rimossa la guida otturatoria atraumatica con alette GYNECARE TVT, ruotare l'impugnatura del tunnelizzatore otturatorio elicoidale e contemporaneamente spostarla verso la linea mediana finché tale impugnatura non si trova perpendicolare al pavimento (osservare la figura 6). *(Nota: non orientare mai l'impugnatura in posizione orizzontale.)*

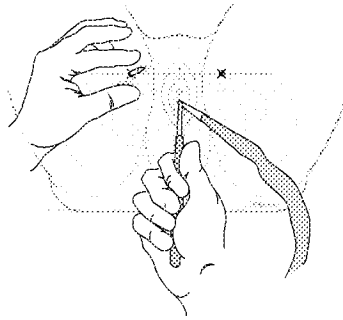


FIGURA 7

14. È necessario far uscire la punta del tunnelizzatore *otturatorio* elicoidale dai punti di uscita determinati precedentemente (*osservare la figura 7*). Può tuttavia essere necessaria una leggera manipolazione della cute. Se precedentemente non è stata eseguita alcuna incisione della cute, eseguirla nel punto in cui la punta del tunnelizzatore *otturatorio* elicoidale preme contro di essa, tendendola. Quando la punta del tubo in plastica fuoriesce dall'apertura della cute, afferrarla con un morsetto e mentre si rende stabile il tubo accanto all'uretra con il pollice, rimuovere il tunnelizzatore *otturatorio* elicoidale con una rotazione inversa dell'impugnatura (*osservare la figura 8*).

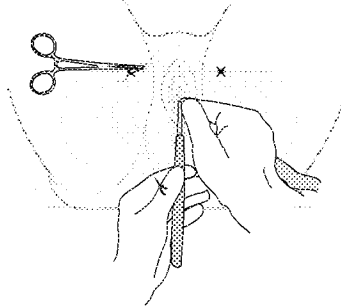


FIGURA 8

15. Tirare completamente il tubo in plastica attraverso la cute, finché non fuoriesce il nastro (*osservare la figura 9*).

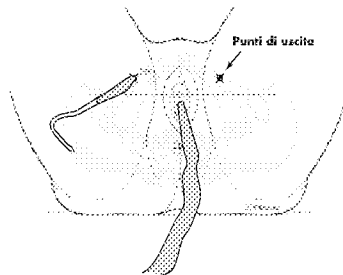


FIGURA 9

16. Ripetere la stessa tecnica nell'altro lato della paziente, verificando che il nastro giaccia piatto sotto l'uretra (*osservare la figura 10*).

(Nota: se si scopre una torsione del nastro, tirare il medesimo e verificare che la torsione non si trovi proprio sotto l'uretra.)

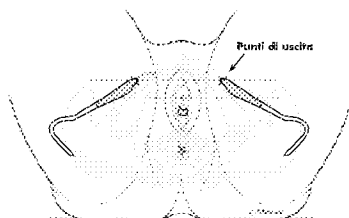


FIGURA 10

17. Una volta estratti entrambi i tubi in plastica attraverso le incisioni della cute, tagliarli dal nastro e dalle guaine in plastica. Posizionare il nastro in modo che sia lento, cioè senza tensione, e si trovi piatto sotto la porzione media dell'uretra. In questa fase è possibile eseguire un test facendo tossire la paziente. Ciò consente una regolazione del nastro, in modo che durante un colpo di tosse vadano perse solo poche gocce di urina (osservare la figura 11).

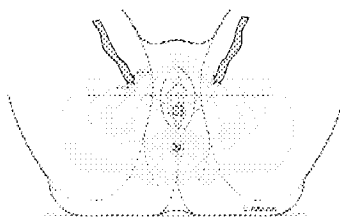


FIGURA 11

Quando il nastro è in posizione, rimuovere la guaina in plastica che copre il nastro. Porre uno strumento smusso (forbici o bisturi) fra l'uretra e il nastro durante la rimozione delle guaine in plastica, diversamente usare altri mezzi adeguati durante la rimozione della guaina allo scopo di evitare di posizionare il nastro con tensione.

(Nota: la rimozione prematura della guaina può rendere difficili le successive regolazioni.)

18. Chiudere l'incisione vaginale dopo aver regolato il nastro. Tagliare le estremità del nastro nei punti di uscita, proprio sotto la cute della coscia interna. Chiudere le incisioni sulla cute con una sutura o con adesivo chirurgico cutaneo.
19. A discrezione del chirurgo, è possibile eseguire una cistoscopia. Se dopo il primo passaggio è stata eseguita una cistoscopia, assicurarsi che la vescica sia vuota prima di iniziare il passaggio del secondo lato. Normalmente non è necessaria alcuna cateterizzazione post-operatoria a permanenza. Incoraggiare la paziente a svuotare la vescica dopo 2-3 ore dall'intervento.

CONTROINDICAZIONI

Come per ogni tipo di chirurgia di sospensione, questa tecnica non deve essere eseguita nelle gestanti. Inoltre, poiché la rete in polipropilene PROLENE non si tenderebbe adeguatamente, questa procedura non deve essere eseguita su pazienti con potenziale incremento ponderale, incluse donne che stanno pianificando una futura gravidanza.

AVVERTENZE E PRECAUZIONI

- Non utilizzare la procedura con il dispositivo otturatorio GYNECARE TVT su pazienti sottoposte a terapia anticoagulante.
- Non utilizzare la procedura con il dispositivo otturatorio GYNECARE TVT su pazienti che presentano un'infezione alle vie urinarie.
- Prima di utilizzare il dispositivo otturatorio GYNECARE TVT, gli utenti dovranno conoscere in modo approfondito le tecniche chirurgiche di sospensione dell'uretra ed essere adeguatamente specializzati nella procedura con il dispositivo otturatorio GYNECARE TVT.
- Attenersi ad una pratica chirurgica riconosciuta per la procedura con il dispositivo otturatorio GYNECARE TVT e per la gestione di ferite infette o contaminate.
- La procedura con il dispositivo otturatorio GYNECARE TVT dovrà essere eseguita con la massima attenzione, avendo cura di evitare grandi vasi, nervi, vescica e intestino. Per ridurre al minimo i rischi è importante conoscere l'anatomia della paziente ed effettuare un passaggio corretto del dispositivo.
- È possibile che si verifichi un'emorragia dopo l'intervento. Prestare attenzione ad eventuali sintomi o segni clinici prima di dimettere la paziente dall'ospedale.
- Sebbene sia improbabile che si verifichino lesioni della vescica con questa tecnica, a discrezione del chirurgo sarà possibile eseguire una cistoscopia.
- Rimuovere le guaine in plastica solo dopo aver posizionato correttamente il nastro.

- Assicurarsi che il nastro sia posizionato sotto la porzione media dell'uretra in assenza di tensione.
- Non eseguire questa procedura se si pensa che il sito chirurgico possa essere infettato o contaminato.
- Poiché non vi sono informazioni cliniche sulla gravidanza dopo l'applicazione di sling sub-uretrale con il sistema otturatorio GYNECARE TVT, informare la paziente che una futura gravidanza potrebbe vanificare gli effetti della procedura chirurgica e che l'incontinenza potrebbe manifestarsi di nuovo.
- Poiché non vi sono informazioni cliniche su parti naturali dopo l'applicazione di sling sub-uretrale con il sistema otturatorio GYNECARE TVT, in caso di gravidanza è necessario prendere in considerazione il parto cesareo.
- Dopo l'intervento, la paziente dovrà astenersi dal sollevare pesi e/o svolgere esercizio fisico (ad es. ciclismo, corsa) per almeno tre o quattro settimane e dovrà evitare rapporti sessuali per un mese. Di solito, la paziente potrà tornare a svolgere le normali attività dopo una o due settimane.
- È necessario avvertire la paziente di contattare immediatamente il medico in caso di disuria, sanguinamento o altri problemi correlati.
- È possibile che si presenti un dolore transitorio alle gambe di durata 24–48 ore, che di solito potrà essere risolto mediante analgesici leggeri.
- Come per altre tecniche per l'incontinenza, dopo l'applicazione della sling sub-uretrale utilizzando il sistema otturatorio GYNECARE TVT, potrebbe di nuovo verificarsi un'instabilità del detrusore. Per ridurre al minimo questo rischio, assicurarsi di aver posizionato il nastro come descritto in precedenza.
- Per evitare danni meccanici alla rete, non mettere in contatto il nastro di PROLENE con punti, clip o fermagli.
- Non risterilizzare il dispositivo otturatorio GYNECARE TVT o qualunque suo componente. Eliminare dispositivi aperti e non usati.
- È possibile somministrare antibiotici di profilassi secondo la procedura usuale del chirurgo.

EFFETTI INDESIDERATI

- Durante il passaggio dell'ago possono verificarsi buchi o lacerazioni di vasi, nervi, vescica, uretra o intestino, che potrebbero necessitare di una riparazione chirurgica.
- È possibile che nel sito della ferita si manifesti un'irritazione transitoria locale o una reazione transitoria da corpo estraneo. Tale reazione può dar luogo a estrusione, erosione, formazione di fistola o infiammazione.
- Come per qualsiasi corpo estraneo, la rete in PROLENE può aggravare un'infezione già esistente. Le guaine in plastica che all'inizio ricoprono la rete in PROLENE servono a ridurre al minimo il rischio di contaminazione.
- Una correzione eccessiva, ad es. troppa tensione sul nastro, può causare un'ostruzione temporanea o permanente delle vie urinarie inferiori.

AZIONI

Studi eseguiti su animali dimostrano che l'impianto della rete PROLENE suscita nei tessuti una reazione infiammatoria minima, di natura transitoria, seguita poi dal deposito di un sottile strato fibroso di tessuto, che può crescere attraverso gli interstizi della maglia, incorporando di conseguenza la maglia nel tessuto adiacente. Il materiale non viene assorbito, né subisce degrado o indebolimento dall'azione degli enzimi tissutali.

CONFEZIONE

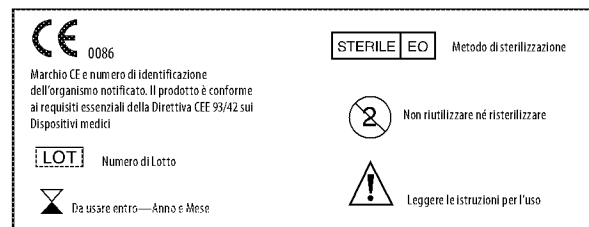
Il sistema otturatorio GYNECARE TVT è fornito sterile (trattato con ossido di etilene) ed è monouso. Non risterilizzare. Il riutilizzo del dispositivo (o di parti di esso) può creare un rischio di degradazione del prodotto e di contaminazione crociata, che possono causare infezioni o trasmissione di patogeni di origine ematica a pazienti e utilizzatori. Non usare se la confezione è stata aperta o danneggiata. Eliminare dispositivi aperti e non usati.

CONSERVAZIONE

Si consiglia di conservare il sistema otturatorio GYNECARE TVT monouso ad una temperatura inferiore a 25 °C, in luogo asciutto e lontano da fonti di calore. Non usare dopo la data di scadenza.

ATTENZIONE: la legge federale statunitense limita la vendita di questo dispositivo ai medici o su prescrizione medica.

SIMBOLI USATI SULL'ETICHETTA



PORTUGUÊS**Sistema obturador GYNECARE TVT™
Apoio sem tensão para incontinência****Dispositivo obturador GYNECARE TVT,
estéril, para uma única utilização****Passadores helicoidais para obturador GYNECARE TVT,
estéreis, para uma única utilização****Guia alado atraumático para obturador GYNECARE TVT,
estéril, para uma única utilização****Por favor, leia atentamente todas as informações.**

O não cumprimento das instruções poderá originar o funcionamento indevido do dispositivo e provocar lesões pessoais.

Importante:

Este folheto informativo destina-se a fornecer instruções para a utilização do sistema obturador GYNECARE TVT™, incluindo o dispositivo obturador, passadores helicoidais e guia alado atraumático GYNECARE TVT. Não constitui uma referência completa sobre a aplicação da técnica cirúrgica de correção da incontinência urinária de esforço (SUI). O dispositivo deve ser usado apenas por médicos especializados no tratamento cirúrgico da incontinência urinária de esforço e, especificamente, na implantação do dispositivo obturador GYNECARE TVT. Estas instruções destinam-se ao uso genérico do dispositivo. Podem ocorrer variações na utilização em procedimentos específicos devido a técnicas individuais e à anatomia da doente.

DESCRIÇÃO

O sistema obturador GYNECARE TVT é um kit esterilizado, destinado a um procedimento numa única doente, composto por:

Dispositivo obturador GYNECARE TVT

O dispositivo obturador GYNECARE TVT consiste num dispositivo estéril, para utilização numa única doente, constituído por uma peça de rede de polipropileno PROLENE™ (faixa), não corada ou de cor azul (azul de ftalocianina, número do índice da cor 74160), com aproximadamente 1,1 cm x 45 cm, revestida por uma bainha de plástico que se sobrepõe no meio. Existem receptáculos de tubo de plástico fixos em cada extremidade. A rede de polipropileno PROLENE é composta por filamentos tecidos de polipropileno obtido por extrusão, cuja composição é idêntica à da sutura cirúrgica de polipropileno não absorvível PROLENE. Este material, quando usado como sutura, demonstrou não ser reactivo e mantém a sua resistência indefinidamente em uso clínico. A rede PROLENE é tecida mediante um processo que entrelaça as uniões de cada fibra e que lhe confere elasticidade em ambas as direcções. Esta propriedade elástica bidireccional permite a adaptação às diversas tensões a que o organismo está sujeito.

Passadores helicoidais GYNECARE TVT

Os passadores helicoidais GYNECARE TVT são dois passadores metálicos curvos em aço inoxidável, dotados de punhos de plástico e concebidos para a colocação do dispositivo obturador GYNECARE TVT. Os passadores helicoidais são fornecidos como unidades esquerda e direita, pré-montados no dispositivo obturador GYNECARE TVT. O passador helicoidal não DEVE ser dobrado ou deformado sob nenhuma forma.

Guia alado atraumático GYNECARE TVT

O guia alado atraumático GYNECARE TVT consiste num instrumento acessório em aço inoxidável que facilita a passagem dos passadores helicoidais GYNECARE TVT através da área de dissecação.

INDICAÇÕES

O dispositivo obturador GYNECARE TVT destina-se a ser utilizado em mulheres, como suporte sub-uretral para o tratamento da incontinência urinária de esforço (SUI), causada por hiper-mobilidade uretral e/ou deficiência do esfíncter intrínseco.

INDICAÇÕES DE UTILIZAÇÃO

(Nota: As posições das mãos mostradas nas ilustrações podem variar.)

1. Coloque a doente na posição de litotomia dorsal, com as ancas em hiperflexão por cima do abdómen. As nádegas devem estar posicionadas justas à extremidade da mesa.
2. O procedimento pode ser efectuado sob anestesia local, regional ou geral.
3. Se desejar, afaste os lábios para facultar uma exposição adicional.
4. Introduza um cateter uretral na bexiga e esvazie a bexiga.

5. Marque os pontos de saída dos tubos de plástico traçando uma linha horizontal ao nível do meato uretral, e uma segunda linha paralelamente e 2 cm acima da primeira linha. Localize os pontos de saída nesta linha, 2 cm por fora das dobras da coxa (a pele pode ser aplainada esticando). Marque os pontos de saída, alternativamente pode ser feita uma incisão de 5 mm–10 mm em cada ponto de saída ou numa fase posterior do procedimento (consulte a Figura 1).

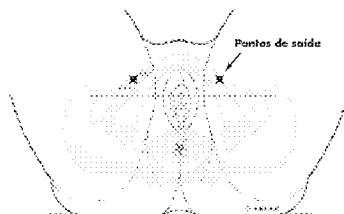


FIGURA 1

6. Utilizando clampes Allis para tração, faça uma incisão de 1 cm na linha média, ao nível da mucosa vaginal, começando 1 cm proximal ao meato uretral.

(Nota: Sugere-se a conclusão da introdução do dispositivo num dos lados antes de se iniciar a dissecação do segundo lado.)

Depois de iniciar a dissecação cortante, prossiga utilizando uma "técnica de empurrar-afastar", para efectuar a dissecação romba, utilizando preferencialmente uma tesoura curva e afiada. O trajecto da dissecação externa deve ser orientado num ângulo de 45° em relação à linha média, com a tesoura orientada no plano horizontal (consulte a Figura 2). Continue a dissecação até à junção entre o corpo do osso púbico e o ramo inferior do púbis (consulte a Figura 2).

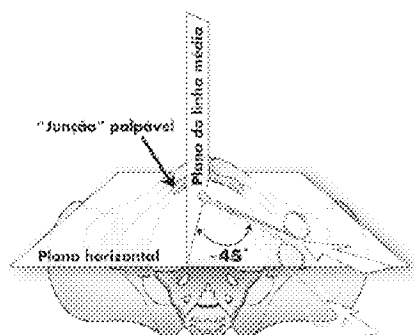


FIGURA 2

Quando atingir a junção entre o corpo do osso púbico e o ramo inferior do púbis, perfure a membrana do obturador. Quando a membrana for perfurada, irá sentir uma perda de resistência. O canal deve ter um diâmetro aproximado de 5 mm–7 mm e uma profundidade inferior a 5 cm. Uma dissecação para além de 5 cm pode permitir uma entrada indesejada no espaço de Retzius. Se não atingir o osso depois de dissecar 5 cm, reavalié o ângulo de dissecação, para confirmar que é correcto.

7. Retire a estação de trabalho de embalagem interior da embalagem exterior. Retire depois o guia alado GYNECARE TVT da estação de trabalho de embalagem (consulte a Figura 3).

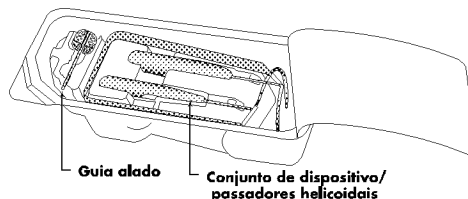


FIGURA 3

8. Introduza o guia alado GYNECARE TVT na área dissecada até que passe pelo ramo inferior do púbis e entre na abertura previamente feita na membrana do obturador. À medida que o guia alado atravessa a membrana do obturador, poderá sentir uma perda de resistência.

Se encontrar dificuldades durante a introdução do guia, volte a confirmar a direcção do trajecto utilizando a tesoura.

(Nota: O lado aberto do guia tem que estar virado para o cirurgião. Se for necessário, a asa curvável pode ser dobrada para aumentar o comprimento do guia, consulte a Figura 5.)

9. Retire o conjunto do dispositivo/passadores helicoidais GYNECARE TVT e o conjunto do dispositivo obturador GYNECARE TVT da embalagem estéril (consulte a Figura 3 para os componentes).

(Nota: Para garantir uma orientação correcta dos passadores helicoidais e faixa, confirme que o logotipo GYNECARE e que o entalhe para o polegar presentes no punho de plástico estão virados para o cirurgião, e que os pontos estão no exterior, virados para o cirurgião. O passador helicoidal na mão esquerda do cirurgião deve ser utilizado no lado direito da doente; consulte a Figura 4.)

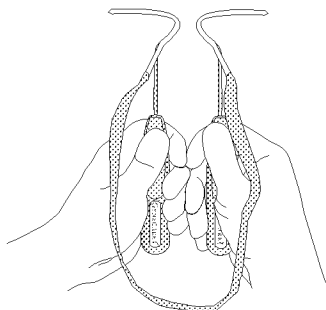


FIGURA 4

10. Coloque um dos passadores helicoidais num pano estéril ou noutro local estéril adequado, até que este seja necessário. Assegure-se de que a faixa não está torcida.
11. Introduza o passador helicoidal GYNECARE TVT correcto na área dissecada, seguindo o canal do guia alado GYNECARE TVT. Empurre o dispositivo para dentro, atravessando e passando ligeiramente a membrana do obturador. Certifique-se de que o punho do dispositivo está orientado de forma a que a ponta recta do passador helicoidal fique alinhada com o canal do guia alado GYNECARE TVT e de que fica nessa orientação até que a ponta atravesse a membrana do obturador (consulte a Figura 5).

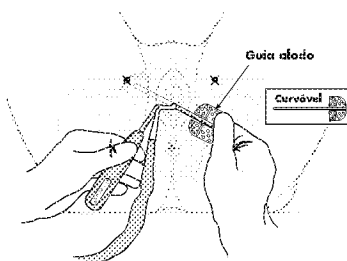


FIGURA 5

12. Uma vez nesta posição, remova o guia alado GYNECARE TVT e conserve-o estéril, para utilização posterior na mesma doente.

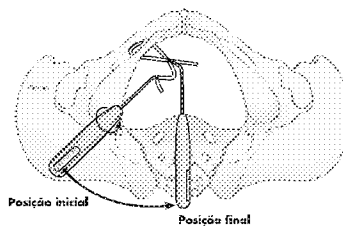


FIGURA 6

13. Depois de retirar o guia alado GYNECARE TVT, rode a punho do passador helicoidal ao mesmo tempo que se desloca para a linha média, até o punho estar vertical relativamente ao chão (consulte a Figura 6). *(Nota: Nunca permita que o punho fique orientado em posição horizontal.)*

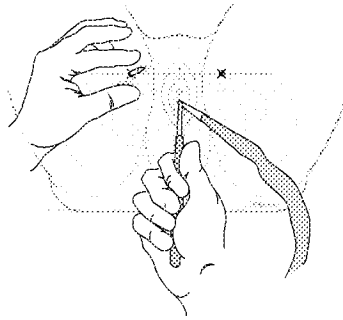


FIGURA 7

14. O ponto do passador helicoidal deve sair próximo dos pontos de saída previamente determinados (consulte a Figura 7). Todavia, poderá ser necessária uma ligeira manipulação da pele. Se não tiver feito previamente a incisão cutânea, faça-a no ponto onde a ponta do passador helicoidal levanta a pele. Quando a ponta do tubo de plástico aparecer na abertura da pele, pegue na ponta afiada do tubo de plástico com um clamp e, ao mesmo tempo que estabiliza o tubo próximo da uretra com o polegar, retire o passador helicoidal fazendo uma rotação inversa do punho (consulte a Figura 8).

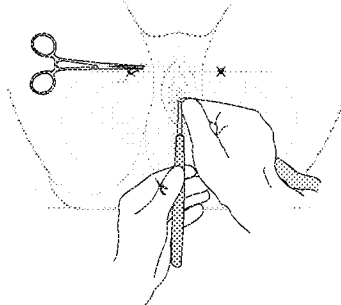


FIGURA 8

15. Puxe completamente o tubo de plástico através da pele, até que apareça a faixa (consulte a Figura 9).

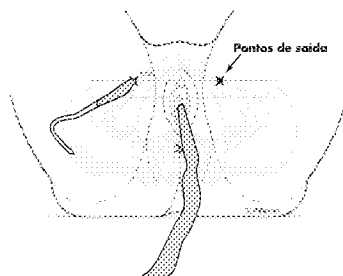


FIGURA 9

16. Repita a técnica no outro lado do doente, assegurando-se de que a faixa assenta plana por baixo da uretra (consulte a Figura 10).

(Nota: Caso se detecte uma torção na faixa, assegure-se de que a torção não fica posicionada por baixo da uretra depois de puxar a fita em excesso.)

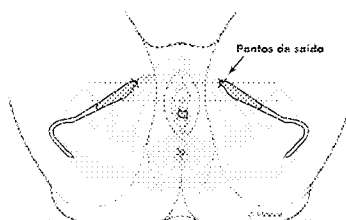


FIGURA 10

17. Quando os dois tubos de plástico tiverem sido extraídos através das incisões cutâneas, corte os tubos de plástico da faixa e bainhas de plástico. Posicione a faixa frouxamente, por exemplo sem tensão, e de modo a ficar plana sob a linha média da uretra. Nesta fase, pode efectuar-se um teste de tosse. Tal permite o ajuste da faixa, de forma a que só se percam algumas gotas de urina durante a tosse (*consulte a Figura 11*).

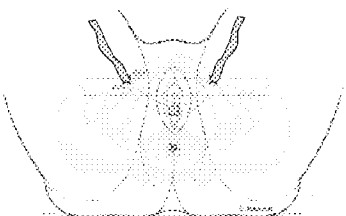


FIGURA 11

Quando a faixa estiver posicionada, retire a bainha de plástico que cobre as faixas. Para evitar o posicionamento da faixa com tensão, coloque um instrumento rombo (por exemplo, tesoura ou pinça) entre a uretra e a faixa durante a remoção das bainhas de plástico, ou utilize outro meio adequado durante a remoção da bainha.

(Nota: A remoção prematura da bainha pode tornar difíceis ajustes subsequentes.)

18. Depois de ajustar faixa, encerre a incisão vaginal. Corte as extremidades da faixa nos pontos de saída, imediatamente por baixo da pele da zona interna da coxa. Encerre as incisões cutâneas com sutura ou adesivo cutâneo cirúrgico.
19. Pode realizar-se uma cistoscopia, de acordo com o critério do cirurgião. Se tiver sido realizada cistoscopia depois da primeira passagem, certifique-se de que a bexiga é esvaziada antes de iniciar a passagem do segundo lado. Não é tipicamente necessária algaliação permanente no pós-operatório. Deve-se encorajar a paciente a tentar urinar duas ou três horas depois da operação.

CONTRA-INDICAÇÕES

Tal como acontece com qualquer cirurgia de suspensão, este procedimento não deve ser efectuado em pacientes grávidas. Além disso, como a rede de polipropileno PROLENE não tem uma capacidade extensível significativa, não deve ser utilizada em pacientes com potencial de crescimento futuro, incluindo pacientes que planeiam uma gravidez futura.

AVISOS E PRECAUÇÕES

- Não usar o procedimento com o obturador GYNECARE TVT em doentes submetidas a terapêutica anti-coagulante.
- Não usar o procedimento com o obturador GYNECARE TVT em doentes que apresentem infecção urinária.
- Os utilizadores devem estar familiarizados com a técnica cirúrgica de suspensão uretral e devem possuir uma formação adequada relativamente ao procedimento com o obturador GYNECARE TVT antes de utilizar o dispositivo obturador GYNECARE TVT.
- Deverá ser utilizada uma técnica cirúrgica apropriada para o procedimento com o obturador GYNECARE TVT, assim como para o tratamento de feridas contaminadas ou infectadas.
- O procedimento com o obturador GYNECARE TVT deverá ser efectuado com extremo cuidado de forma a evitar vasos de grande calibre, nervos, a bexiga e os intestinos. O facto de ter atenção à anatomia da doente e à passagem adequada do dispositivo irá minimizar os riscos.
- Pode ocorrer hemorragia no pós-operatório. Ter atenção a quaisquer sintomas ou sinais antes de dar alta à doente.
- Embora seja improvável que ocorram lesões vesicais com esta técnica, pode ser realizada uma cistoscopia de acordo com o critério do cirurgião.
- Não retirar as bainhas de plástico até que a faixa esteja colocada de forma apropriada.
- Assegurar-se de que a faixa está colocada sem tensão sob a linha média da uretra.
- Não realizar este procedimento caso se pense que o local cirúrgico pode estar infectado ou contaminado.

- Dado que não se encontram disponíveis quaisquer informações relativas a gravidez após um procedimento de suspensão sub-uretral com o sistema obturador GYNECARE TVT, a doente deverá ser aconselhada de que uma futura gravidez poderá anular os efeitos do procedimento cirúrgico e a doente poderá voltar a ser incontinente.
- Dado que não se encontram disponíveis quaisquer informações clínicas relativas a parto por via vaginal após um procedimento de suspensão sub-uretral com o sistema obturador GYNECARE TVT, em caso gravidez deve considerar-se o parto por cesariana.
- No pós-operatório, deverá ser recomendado à doente que não levante pesos e/ou faça exercícios físicos (como ciclismo e correr) durante pelo menos três a quatro semanas, e que não tenha relações sexuais durante um mês. A doente poderá habitualmente voltar a outras actividades normais após uma ou duas semanas.
- Se ocorrer disúria, hemorragia ou outros problemas, a doente deverá ser instruída a contactar imediatamente o cirurgião.
- Pode ocorrer dor transitória nas pernas, com duração de 24 a 48 horas, que pode ser habitualmente controlada com analgésicos fracos.
- Como os demais procedimentos para a incontinência, após um procedimento de suspensão sub-uretral com o sistema obturador GYNECARE TVT pode ocorrer instabilidade do detrusor de novo. Para minimizar este risco, certifique-se de que coloca a faixa conforme acima descrito.
- Evitar o contacto da rede PROLENE com agafros, pinças ou clampes de nenhum tipo, uma vez que isso poderá causar danos mecânicos na rede.
- Não reesterilize o dispositivo obturador GYNECARE TVT nem os seus componentes. Descartar os dispositivos abertos, que tenham sido utilizados ou não.
- Podem ser administrados antibióticos profilácticos, de acordo com a prática habitual do cirurgião.

REAÇÕES ADVERSAS

- Podem ocorrer perfurações ou lacerações de vasos, nervos, bexiga, uretra ou intestino durante a passagem da agulha, que podem exigir reparação cirúrgica.
- Pode ocorrer uma irritação transitória no local da ferida e uma reacção transitória a corpo estranho. Esta reacção poderia causar extrusão, erosão, formação de fistulas e inflamação.
- Tal como acontece com qualquer corpo estranho, a rede PROLENE poderá agravar uma infecção existente. As bainhas de plástico que cobrem inicialmente a rede PROLENE têm a finalidade de reduzir ao mínimo o risco de contaminação.
- Uma correcção excessiva, isto é, a aplicação de demasiada tensão na faixa, pode provocar uma obstrução temporária ou permanente das vias urinárias inferiores.

ACTUAÇÃO

Os estudos em animais revelam que a implantação de PROLENE provoca uma reacção inflamatória mínima nos tecidos, a qual é transitória e é seguida pela deposição de uma fina camada de tecido fibroso que pode crescer através dos interstícios da rede, incorporando deste modo a rede nos tecidos adjacentes. O material não é absorvido nem está sujeito a degradação ou enfraquecimento pela acção das enzimas dos tecidos.

APRESENTAÇÃO

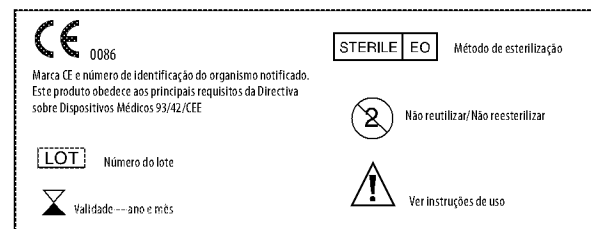
O sistema obturador GYNECARE TVT é fornecido esterilizado (óxido de etileno), para uma única utilização. Não reesterilize. A reutilização deste dispositivo (ou de partes deste dispositivo) pode criar um risco de degradação do produto e contaminação cruzada, o que pode conduzir a infecção ou transmissão de agentes patogénicos transmitidos pelo sangue aos doentes e utilizadores. Não usar se a embalagem estiver aberta ou danificada. Descartar os dispositivos abertos, que tenham sido utilizados ou não.

ARMAZENAMENTO

As condições de armazenamento recomendadas para o sistema obturador GYNECARE TVT de uso único são a uma temperatura inferior a 25 °C, em local seco e fresco. Não usar findo o prazo de validade.

CUIDADO: A lei federal (dos Estados Unidos da América) só permite a venda deste dispositivo a médicos ou sob receita destes.

SÍMBOLOS UTILIZADOS NOS RÓTULOS



ESPAÑOL**Sistema obturador GYNECARE TVT™
Protector sin tensión para la incontinencia****Dispositivo del obturador GYNECARE TVT,
estéril para un solo uso****Pasadores helicoidales del obturador GYNECARE TVT,
estériles para un solo uso****Guía con aletas atraumática del obturador
GYNECARE TVT, estéril para un solo uso****Por favor lea con atención toda la información.**

De no seguir las instrucciones correctamente, el dispositivo podría no funcionar de forma adecuada e incluso causar lesiones personales.

Importante:

Este manual tiene el fin de proveer instrucciones para el uso del sistema obturador GYNECARE TVT™, incluyendo el dispositivo, los pasadores helicoidales y la guía con aletas atraumática del obturador GYNECARE TVT. No es una guía completa para técnicas quirúrgicas para la corrección de la incontinencia urinaria de esfuerzo. El dispositivo debe ser empleado solamente por médicos que cuenten con la formación necesaria para el tratamiento quirúrgico de la incontinencia urinaria de esfuerzo y, específicamente, para la implantación del dispositivo del obturador GYNECARE TVT. Estas instrucciones se refieren al uso general del dispositivo. Puede haber variantes en el uso en procedimientos específicos debido al uso de técnicas individuales y a la anatomía de la paciente.

DESCRIPCIÓN

El sistema obturador GYNECARE TVT es un kit de procedimiento estéril para uso en una sola paciente que consta de los siguientes elementos:

Dispositivo del obturador GYNECARE TVT

El dispositivo del obturador GYNECARE TVT es un dispositivo estéril para uso en una sola paciente. Consta de una pieza de malla (banda) de polipropileno PROLENE™ sin teñir o de color azul (azul ftalocianina, número 74160) de aproximadamente 1,1 cm x 45 cm cubierta con una vaina de plástico superpuesta en el medio y receptáculos tubulares plásticos en cada extremo. La malla de polipropileno PROLENE está hecha de filamentos tejidos de hebras de propileno extrusionado, cuya composición es idéntica a la utilizada en las suturas quirúrgicas no absorbibles de polipropileno PROLENE. Según se ha comprobado, este material no es reactivo cuando se emplea como sutura y retiene su resistencia indefinidamente en el uso clínico. La malla de PROLENE está tejida mediante un proceso que entrelaza la unión de cada fibra y proporciona elasticidad en ambas direcciones. Esta elasticidad bidireccional permite la adaptación a los diferentes niveles de tensión presentes en el cuerpo.

Pasadores helicoidales GYNECARE TVT

Los pasadores helicoidales GYNECARE TVT son dos pasadores de alambre curvos de acero inoxidable con mangos de plástico diseñados para aplicar el dispositivo del obturador GYNECARE TVT. Los pasadores helicoidales se suministran como una unidad izquierda y una unidad derecha y vienen previamente montadas al dispositivo del obturador GYNECARE TVT. Los pasadores helicoidales no DEBEN doblarse ni deformarse de ninguna manera.

Guía con aletas atraumática GYNECARE TVT

La guía con aletas atraumática GYNECARE TVT es un instrumento accesorio de acero inoxidable que facilita el pasaje de los pasadores helicoidales GYNECARE TVT por el área de disección.

INDICACIONES

El dispositivo del obturador GYNECARE TVT está indicado como cabestrillo suburetral para el tratamiento de mujeres con incontinencia urinaria de esfuerzo causada por la hipermovilidad uretral y/o deficiencia intrínseca del esfínter.

INSTRUCCIONES DE USO

(Nota: las posiciones de las manos que se ilustran en las figuras pueden variar.)

1. Coloque a la paciente en la posición de litotomía dorsal con las caderas hiperflexionadas sobre el abdomen. Las nalgas deben colocarse al nivel del borde de la mesa.
2. El procedimiento puede llevarse a cabo bajo anestesia local, pero también puede efectuarse usando anestesia regional o general.
3. Si lo desea, retraiga los labios para obtener una mayor exposición.
4. Introduzca un catéter uretral en la vejiga y vacíela.

5. Marque los puntos de salida de los tubos plásticos trazando una línea horizontal al nivel del meato uretral y una segunda línea paralela 2 cm por encima de la primera línea. Ubique los puntos de salida sobre esta línea, a 2 cm de los lados de los pliegues del muslo (puede estirarse la piel para alisarla). Marque los puntos de salida. Como alternativa, puede realizarse una incisión de 5 mm–10 mm en cada punto de salida o en una etapa posterior del procedimiento (vea la figura 1).

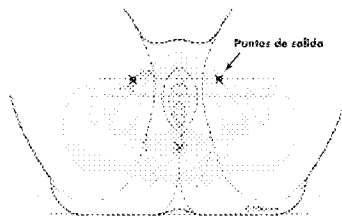


FIGURA 1

6. Utilizando un par de pinzas Allis para tracción, haga una incisión de 1 cm de largo en la línea media de la mucosa vaginal, comenzando a 1 cm en posición proximal al meato uretral.

(Nota: se recomienda finalizar la inserción del dispositivo sobre un lado antes de comenzar con la disección del segundo lado.)

Después de iniciar una disección cortante, continúe usando una "técnica de empuje-separación" para realizar una disección roma preferentemente usando tijeras curvas puntiagudas. El recorrido de la disección lateral debe formar un ángulo de 45° respecto de la línea media, con las tijeras orientadas sobre el plano horizontal (vea la figura 2). Continúe la disección hacia la unión entre el cuerpo de los huesos púbicos y la rama púbica inferior (vea la figura 2).

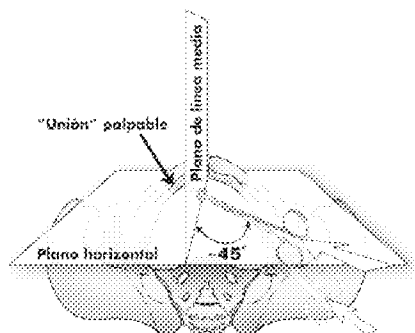


FIGURA 2

Cuando llegue a la unión entre el cuerpo de los huesos púbicos y la rama púbica inferior, perforo la membrana del obturador. Es posible que sienta una pérdida de resistencia al perforar la membrana. El canal debe tener un diámetro de aproximadamente 5 mm–7 mm y una profundidad de 5 cm como máximo. Una disección más profunda podría permitir el ingreso accidental en el espacio de Retzius. Si no llega al hueso después de una disección de 5 cm, asegúrese de que el ángulo de disección es correcto.

7. Retire la estación de trabajo del envase interno del envase externo. A continuación, retire la guía con aletas GYNECARE TVT de la estación de trabajo del envase (vea la figura 3).

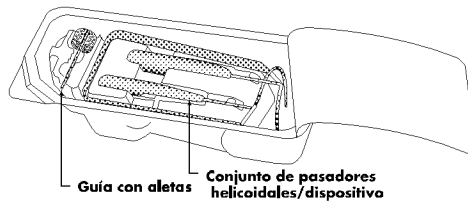


FIGURA 3

8. Introduzca la guía con aletas GYNECARE TVT en el área disecada pasando la rama púbica inferior hasta que ingrese en la abertura previamente realizada en la membrana del obturador. Es posible que sienta una pérdida de resistencia a medida que la guía con aletas pasa por la membrana del obturador.

Si encuentra dificultades al introducir la guía, verifique la dirección del tracto con las tijeras.

(Nota: el lado abierto de la guía debe estar de cara al cirujano. La pestaña flexible puede doblarse para aumentar la longitud de la guía en caso de ser necesario; vea la figura 5.)

9. Retire el conjunto de pasadores helicoidales/dispositivo GYNECARE TVT y el conjunto del dispositivo del obturador GYNECARE TVT del envase estéril (vea los componentes en la figura 3).

(Nota: para asegurar la correcta orientación de los pasadores helicoidales y la banda, cerciórese de que el logotipo de GYNECARE y la muesca para el dedo pulgar sobre el mango de plástico queden de cara al cirujano y que las puntas se encuentren sobre el lado exterior, también de cara al cirujano. El pasador helicoidal en la mano izquierda del cirujano debe utilizarse sobre el lado derecho de la paciente; vea la figura 4.)

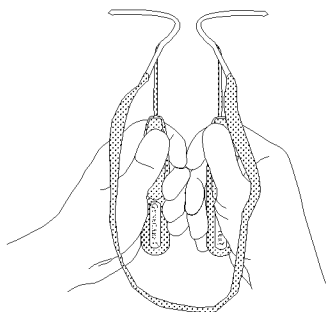


FIGURA 4

10. Coloque uno de los pasadores helicoidales sobre el paño estéril u otro lugar estéril adecuado hasta que sea necesario utilizarlo. Asegúrese de que la banda no está torcida.
11. Introduzca el pasador helicoidal GYNECARE TVT correcto en el área disecada siguiendo el canal de la guía con aletas GYNECARE TVT. Empuje el dispositivo hacia adelante, atravesando y pasando ligeramente la membrana del obturador. Asegúrese de que el mango del dispositivo está orientado de modo tal que la punta recta del pasador helicoidal quede alineada con el canal de la guía con aletas GYNECARE TVT y que se mantiene en esa orientación hasta que la punta haya atravesado la membrana del obturador (vea la figura 5).

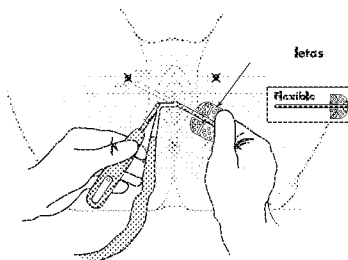


FIGURA 5

12. Una vez en esta posición, retire la guía con aletas GYNECARE TVT y consérvela estéril para su uso posterior en la misma paciente.

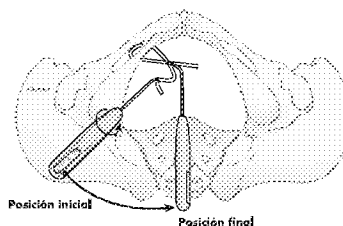


FIGURA 6

13. Una vez retirada la guía con aletas GYNECARE TVT, gire el mango del pasador helicoidal mientras mueve el mango hacia la línea media hasta que quede perpendicular al suelo (vea la figura 6). **(Nota: no permita nunca que el mango quede orientado en posición horizontal.)**

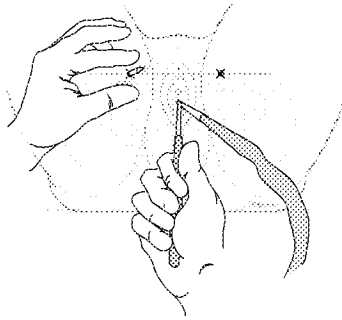


FIGURA 7

14. La punta del pasador helicoidal debe salir cerca de los puntos de salida previamente determinados (vea la figura 7). No obstante, puede requerirse una ligera manipulación de la piel. Si no se ha realizado antes la incisión en la piel, hágala en este momento en el lugar en que la punta del pasador sobresale por debajo de la piel. Cuando la punta del tubo plástico aparezca por la abertura de la piel, sujétela con una pinza y, mientras estabiliza el tubo cerca de la uretra con el dedo pulgar, retire el pasador helicoidal haciendo girar el mango en sentido inverso (vea la figura 8).

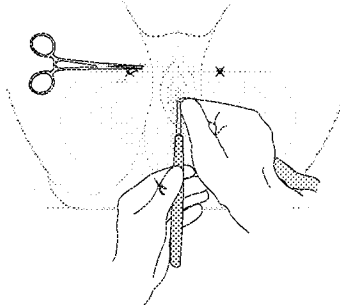


FIGURA 8

15. Tire del tubo plástico hasta que pase completamente a través de la piel y aparezca la banda (vea la figura 9).

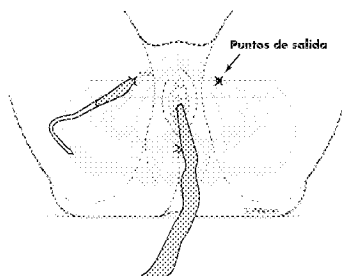


FIGURA 9

16. Repita la técnica sobre el otro lado de la paciente, asegurándose de que la banda queda en posición horizontal debajo de la uretra (vea la figura 10).

(Nota: en caso de descubrir que la banda está torcida, asegúrese de que no se encuentra torcida debajo de la uretra después de haber pasado la banda excedente.)

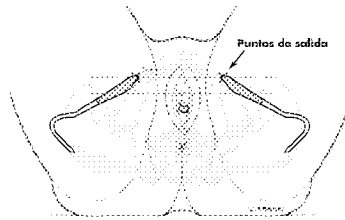


FIGURA 10

17. Una vez extraídos ambos tubos plásticos a través de las incisiones en la piel, corte los tubos de la banda y las vainas plásticas. Ubique la banda de forma floja, sin tensarla, y en posición horizontal debajo de la uretra media. En este momento puede realizarse la prueba de la tos. Esta prueba permitirá ajustar la banda para que sólo se pierdan unas gotas de orina al toser (vea la figura 11).

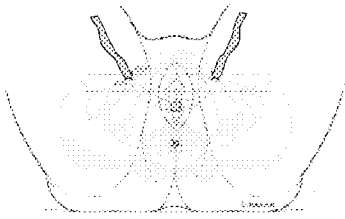


FIGURA 11

Cuando la banda esté ubicada, retire la vaina plástica que cubre las bandas. Para evitar la tensión en la banda, se debe colocar un instrumento romo (por ejemplo, tijeras o fórceps) entre la uretra y la banda mientras se retiran las vainas plásticas, o bien utilizar otro método adecuado.

(Nota: la retirada prematura de la vaina puede dificultar los ajustes subsiguientes.)

18. Después de ajustar la banda cierre la incisión vaginal. Recorte los extremos de la banda en los puntos de salida exactamente debajo de la piel del muslo interior. Cierre las incisiones en la piel con sutura o adhesivo quirúrgico para piel.
19. Puede realizarse una cistoscopia a discreción del cirujano. Si se realizó una cistoscopia después del primer pasaje, asegúrese de vaciar la vejiga antes de iniciar el pasaje del segundo lado. Después de este procedimiento, normalmente no es necesario el cateterismo postoperatorio. Intente convencer a la paciente para que pruebe a vaciar la vejiga 2 a 3 horas después de la operación.

CONTRAINDICACIONES

Al igual que con cualquier cirugía de suspensión, este procedimiento no debe realizarse en pacientes embarazadas. Además, dado que la malla de polipropileno PROLENE no se estirará de forma significativa, este procedimiento no debe realizarse en pacientes con potencial de crecimiento futuro, incluyendo mujeres que tengan pensado quedar embarazadas en el futuro.

ADVERTENCIAS Y PRECAUCIONES

- No usar el procedimiento obturador GYNECARE TVT en pacientes sometidas a terapia de anticoagulación.
- No usar el procedimiento obturador GYNECARE TVT en pacientes con infección en el tracto urinario.
- Los usuarios deben familiarizarse con la técnica quirúrgica para suspensiones uretrales y recibir la formación adecuada en el procedimiento obturador GYNECARE TVT antes de utilizar el dispositivo del obturador GYNECARE TVT.
- Se deben emplear prácticas quirúrgicas aceptables para el procedimiento obturador GYNECARE TVT, así como para el tratamiento de heridas contaminadas o infectadas.
- El procedimiento obturador GYNECARE TVT debe realizarse con cuidado para evitar dañar vasos grandes, nervios, la vejiga y los intestinos. Prestando atención a la anatomía local y pasando las agujas adecuadamente se reducen los riesgos al mínimo.
- Puede producirse hemorragia después de la intervención. Observe cualquier síntoma o indicio antes de dar de alta a la paciente.
- Aunque es poco probable que se produzcan lesiones en la vejiga con esta técnica, puede realizarse una cistoscopia a discreción del cirujano.
- No retirar las vainas de plástico hasta que la banda se haya situado correctamente.
- Cerciorarse de que la banda esté colocada sin tensión bajo la parte media de la uretra.
- No realizar este procedimiento si cree que el sitio quirúrgico puede estar infectado o contaminado.

- Debido a que no se cuenta con información clínica sobre el embarazo después de un procedimiento de cabestrillo suburetral con el sistema obturador GYNECARE TVT, debe informarse a la paciente que los embarazos futuros pueden anular los efectos del procedimiento quirúrgico y que podría volver a ser incontinente.
- Debido a que no se cuenta con información clínica acerca del parto vaginal después de un procedimiento de cabestrillo suburetral con el sistema obturador GYNECARE TVT, debe considerarse una cesárea en caso de embarazo.
- Debe recomendarse a la paciente que, después de la operación, no levante objetos pesados ni haga ejercicio (por ejemplo, ir en bicicleta o correr) durante al menos tres o cuatro semanas y que se abstenga de realizar actividad sexual durante un mes. La paciente puede realizar cualquier otra actividad normal después de una o dos semanas.
- Debe indicarse a la paciente que llame al cirujano inmediatamente en caso de disuria, hemorragia u otros problemas.
- Puede producirse dolor temporal en la pierna con una duración de 24 a 48 horas pero, por lo general, puede tratarse con analgésicos leves.
- Al igual que con otros procedimientos de tratamiento de la incontinencia, puede producirse inestabilidad de novo del detrusor después de un procedimiento de cabestrillo uretral utilizando el sistema obturador GYNECARE TVT. Para reducir este riesgo, asegúrese de colocar la banda como se describe en los pasos anteriores.
- No tocar la banda de PROLENE con grapas, clips o pinzas de ningún tipo, ya que se podría causar algún daño mecánico a la malla.
- No reesterilizar el dispositivo del obturador GYNECARE TVT ni sus componentes. Desechar los dispositivos abiertos no utilizados.
- Pueden administrarse antibióticos profilácticos según la práctica habitual del cirujano.

REACCIONES ADVERSAS

- Las laceraciones o perforaciones en vasos, nervios, la vejiga, la uretra o los intestinos durante la introducción de la aguja pueden necesitar reparación quirúrgica.
- Puede presentarse una irritación local transitoria en la herida y una respuesta transitoria al cuerpo extraño. Esta respuesta podría causar extrusión, erosión, formación de fístulas e inflamación.
- Al igual que cualquier cuerpo extraño, la malla de PROLENE podría potenciar una infección existente. La vaina de plástico que cubre inicialmente la malla de PROLENE tiene el fin de reducir al mínimo el riesgo de contaminación.
- El exceso de corrección, es decir, la aplicación de demasiada tensión a la banda, puede causar una obstrucción temporal o permanente de las vías urinarias inferiores.

ACCIONES

Los estudios en animales indican que la implantación de PROLENE provoca una reacción inflamatoria mínima en los tejidos de carácter transitorio, seguida por la deposición de una capa delgada de tejido fibroso que puede crecer a través de los intersticios de la malla, incorporando de este modo la malla en los tejidos adyacentes. El material no es absorbido ni sometido a degradación o debilitamiento por la acción de las enzimas de los tejidos.

PRESENTACIÓN

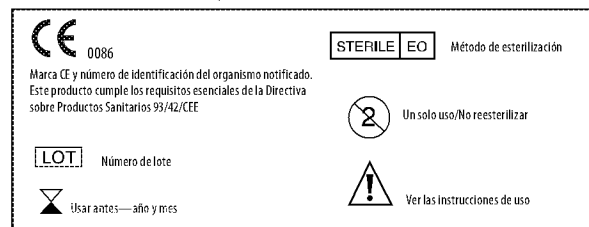
El sistema obturador GYNECARE TVT se suministra esterilizado (por óxido de etileno) para un solo uso. No reesterilizar. La reutilización de este dispositivo (o partes del mismo) puede crear un riesgo de degradación del producto y contaminación cruzada, lo que puede llevar a infecciones o transmisión de patógenos sanguíneos a pacientes y usuarios. No utilizar si el paquete está abierto o dañado. Desechar los dispositivos abiertos no utilizados.

ALMACENAJE

Se recomienda almacenar el sistema obturador GYNECARE TVT de un solo uso a temperaturas de menos de 25 °C, alejado de la humedad y del calor directo. No usarlo después de la fecha de caducidad.

ATENCIÓN: las leyes federales de los EE.UU. restringen la venta de este dispositivo al personal facultativo o bajo su prescripción.

SÍMBOLOS EMPLEADOS EN LAS ETIQUETAS



SVENSKA**GYNECARE TVT™ obturatoriabandsystem
Tensionsfritt stöd för behandling av inkontinens****GYNECARE TVT obturatoriaband,
sterilt, för engångsbruk****GYNECARE TVT spiralformade nålar för införing
av obturatoriaband,
sterila, för engångsbruk****GYNECARE TVT atraumatisk vingförsedd guide
för obturatoriaband,
steril, för engångsbruk****Läs noga igenom all information.**

Underlåtenhet att noggrant följa dessa anvisningar kan resultera i att instrumenten inte fungerar korrekt och kan även medföra skador.

Viktigt:

Denna bipacksedel innehåller instruktioner för användning av GYNECARE TVT™ obturatoriabandsystem, inklusive GYNECARE TVT obturatoriaband, spiralformade nålar och atraumatisk vingförsedd guide. Bipacksedeln utgör ej någon fullständig referensskrift för kirurgisk teknik vid behandling av ansträngningsinkontinens. Produkten får endast användas av läkare med utbildning i kirurgisk behandling av ansträngningsinkontinens och specifik utbildning i implantation av GYNECARE TVT obturatoriaband. Dessa anvisningar är avsedda för den användning av denna produkt som i allmänhet tillämpas. Andra användningssätt kan förekomma vid specifika typer av ingrepp, avhängigt individuell teknik och patientens anatomi.

BESKRIVNING

GYNECARE TVT obturatoriabandsystem är en steril sats avsedd för ingrepp på en patient, och innehåller:

GYNECARE TVT obturatoriaband

GYNECARE TVT obturatoriaband är en steril produkt avsedd för användning till en patient, som består av ett ofärgat eller blått (ftalocyaninblått, färgindexnummer 74160) PROLENE™ polypropylen nät (band), cirka 1,1 cm x 45 cm, inneslutet i ett plasthölje som går omlott i mitten. I varje ände finns ett plaströr fastsatt. PROLENE polypropylen nät är framställt av stickade filament av extruderade polypropylenfibrer, av exakt samma sammansättning som den som används i PROLENE icke-resorberbar polypropylen sutur. Detta material har vid användning som suturmaterial rapporterats vara icke-reaktivt och behålla sin styrka i obegränsad tid vid klinisk användning. PROLENE-nätet är stickat med användning av en teknik som sammanlänkar varje fiberkorsning, vilket ger elasticitet i båda riktningarna. Denna tvåvägselasticitet möjliggör anpassning till de olika påfrestningar som kan förekomma i kroppen.

GYNECARE TVT spiralformade nålar

GYNECARE TVT spiralformade nålar utgörs av två införingsnålar av böjd rostfri stål vajer med plasthandtag, designade för införing av GYNECARE TVT obturatoriaband. De spiralformade nålarna tillhandahålls i form av en högersidig och en vänstersidig enhet, hopmonterade med GYNECARE TVT obturatoriaband. Den spiralformade nålen FÅR ej böjas eller på något sätt omformas.

GYNECARE TVT atraumatisk vingförsedd guide

GYNECARE TVT atraumatisk vingförsedd guide är ett tillbehör av rostfritt stål som används för att underlätta passagen av GYNECARE TVT spiralformade nålar genom dissektionsområdet.

INDIKATIONER

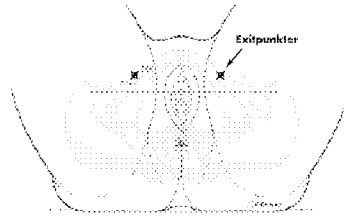
GYNECARE TVT obturatoriaband är avsett att användas som en suburetral slynga för behandling av kvinnor med ansträngningsinkontinens till följd av hypermobil uretra och/eller sfinkterinsufficiens.

BRUKSANVISNING

(Obs! Handställningarna som visas i illustrationerna kan variera.)

1. Placera patienten i dorsalt litotomiläge med höftlederna hyperflektade över buken. Klinkorna skall vara placerade så att de är jäms med bordskanten.
2. Ingreppet kan utföras i lokal-, regional eller allmän anestesi.
3. Dra vid behov tillbaka blygdläpparna för ytterligare exponering.
4. För in en uretrakateter i blåsan och töm blåsan.

5. Markera exitpunkterna för plaströren genom att rita en horisontell linje i nivå med uretrala meatus och en andra linje 2 cm ovanför och parallell med den första linjen. Lokalisera exitpunkterna på denna andra linje, 2 cm lateralt om lårvecken (huden kan sträckas så att den plattas ut). Markera exitpunkterna. Alternativt kan en 5 mm–10 mm incision läggas vid varje exitpunkt eller vid ett senare skede under ingreppet (se figur 1).

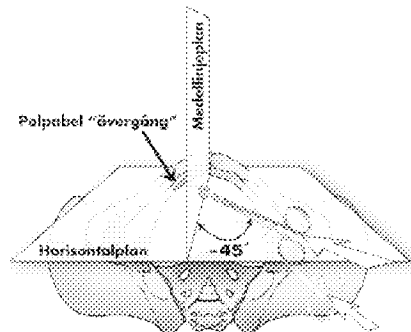


FIGUR 1

6. Använd en Allis-tång för att anbringa traktion och lägg en 1 cm lång incision i medellinjen i vaginalslemhinnan med start 1 cm proximalt om uretrala meatus.

(Obs! Vi föreslår att införandet av bandet fullförs på ena sidan innan dissektionen påbörjas på den andra sidan.)

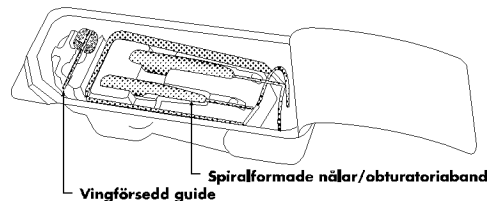
Efter att ha påbörjat skarp dissektion, fortsätt med hjälp av "push-spread"-teknik att utföra trubbig dissektion, helst med en spetsig, böjd sax. Den laterala dissektionen skall gå i en bana orienterad i 45° vinkel från medellinjen, med saxen orienterad i horisontalplanet (se figur 2). Försätt dissektionen i riktning mot övergången mellan corpus ossis pubis och ramus inferior ossis pubis (se figur 2).



FIGUR 2

När övergången mellan corpus ossis pubis och ramus inferior ossis pubis har nåtts, perforeras membrana obturatoria. När membranet perforeras känns en plötslig minskning av motståndet. Kanalen bör vara cirka 5 mm–7 mm i diameter och ej djupare än 5 cm. Djupare dissektion än 5 cm kan medföra att man oavsiktligt kommer in i det prevesikala spatiet. Om benet inte har nåtts efter 5 cm dissektion bör det kontrolleras att dissektionsvinkeln är korrekt.

7. Lyft ut den inre förpackningens arbetsstation från den yttre förpackningen. Lyft sedan ut GYNECARE TVT vingförsedd guide ur förpackningen (se figur 3).



FIGUR 3

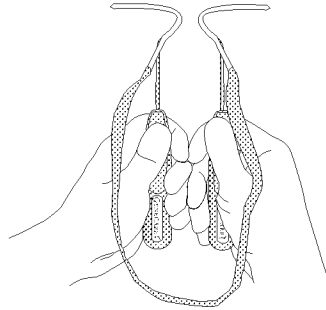
8. För in GYNECARE TVT vingförsedd guide i den dissekerade kanalen tills den passerar ramus inferior ossis pubis och kommer in i den tidigare gjorda öppningen i membrana obturatoria. När den vingförsedda guiden passerar membrana obturatoria kan en plötslig minskning av motståndet kännas.

Vid svårigheter vid införandet av guiden skall kanalens riktning kontrolleras med hjälp av saxen.

(Obs! Guidens kanalsida måste vara vänd mot kirurgen. Den böjbara fliken kan vid behov böjas så att guiden förlängs, se figur 5.)

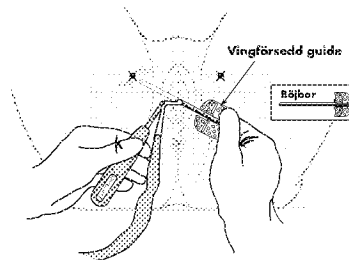
9. Ta ut GYNECARE TVT obturatoriaband tillsammans med de spiralformade nålarna och plaströren ur sterilförpackningen (se figur 3 för en illustration av komponenterna).

(Obs! För att säkerställa att de spiralformade nålarna och bandet är orienterade korrekt skall det kontrolleras att GYNECARE-logon och tumgreppet på plasthandtagen är vända mot kirurgen och att plaströrens spetsiga ändar är vända utåt. Den spiralformade nålen som kirurgen håller i vänster hand måste användas på patientens högra sida; se figur 4.)



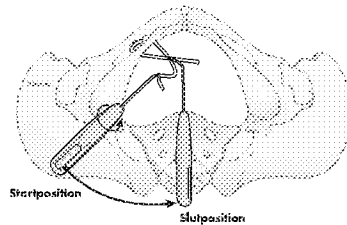
FIGUR 4

10. Placera en av de spiralformade nålarna på den sterila duken eller annan lämplig steril plats, tills den skall användas. Säkerställ att bandet inte är vridet.
11. För in korrekt GYNECARE TVT spiralformad nål i det dissekerade området genom att följa kanalen i GYNECARE TVT vingförsedd guide. Skjut in bandet så att det passerar igenom och går något förbi membrana obturatoria. Kontrollera att handtaget är orienterat så att den spiralformade nålens raka ände är inriktad längs med kanalen i GYNECARE TVT vingförsedd guide och förblir orienterad på detta sätt tills spetsen passerar membrana obturatoria (se figur 5).



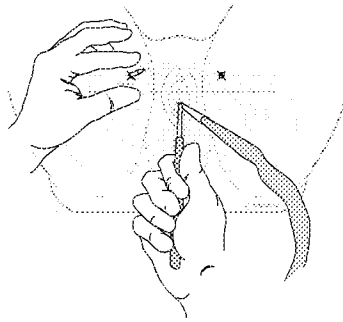
FIGUR 5

12. Avlägsna GYNECARE TVT vingförsedd guide i detta läge och håll den steril för senare användning till samma patient.



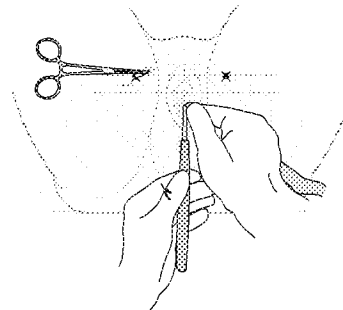
FIGUR 6

13. Efter att GYNECARE TVT vingförsedd guide har avlägsnats, vrid den spiralformade nålens handtag samtidigt som handtaget förs mot medellinjen vertikalt mot golvet (se figur 6). **(Obs! Handtaget får aldrig placeras horisontellt.)**



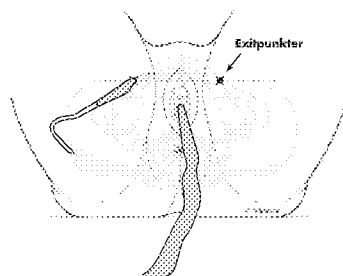
FIGUR 7

14. Den spiralformade nålens spets skall komma ut intill den tidigare markerade exitpunkten (se figur 7). En lätt manipulering av huden kan dock krävas. Om en hudincision inte har lagts tidigare läggs en incision vid den punkt där den spiralformade nålens spets ses under huden. När plaströrets ände kommer fram i hudöppningen sätts en klämma över plaströrets spetsiga ände och den spiralformade nålen avlägsnas genom att handtaget vrids i motsatt riktning mot tidigare, samtidigt som röret stabiliseras intill uretra med tummen (se figur 8).



FIGUR 8

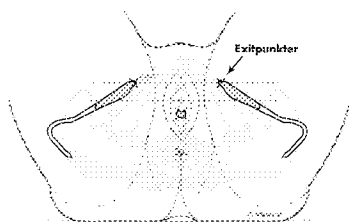
15. Dra ut plaströret helt genom huden tills bandet framträder (se figur 9).



FIGUR 9

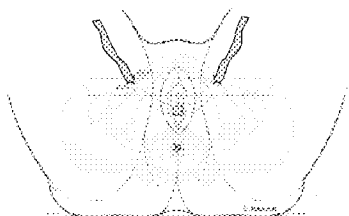
16. Upprepa förfarandet på patientens andra sida och se samtidigt till att bandet ligger plant under uretra (se figur 10).

(Obs! Om det upptäcks att bandet är vridet på något ställe skall det säkerställas att vridningen inte ligger under uretra efter att den extra bandlängden har dragits igenom.)



FIGUR 10

17. Efter att båda plaströren har extraherats via hudincisionerna kapas plaströren av från bandet och plasthöljerna. Placera bandet löst, dvs. utan spänning, och plant under uretras mittersta del. I detta skede kan en hosttest utföras. Bandet kan nu justeras så att endast ett par droppar urin rinner ut när patienten hostar (se figur 11).



FIGUR 11

När bandet är i korrekt läge avlägsnas plasthöljet som skyddar bandet. Placera ett trubbigt instrument (t.ex. sax eller tång) mellan uretra och bandet under det att plasthöljerna avlägsnas, eller använd lämpligt sätt för att avlägsna hylsan utan att skapa spänning i samband med placeringen av bandet.

(Obs! Om plasthöljet avlägsnas för tidigt kan senare justering försvåras.)

18. Efter att bandet har justerats sluts vaginalincisionen. Kapa bandändarna vid exitpunkterna straxt under huden på lårets insida. Slut hudincisionerna med sutur eller kirurgiskt vävnadslim.
19. Cystoskopi kan utföras efter kirurgens bedömning. Om cystoskopi utfördes efter den första passagen skall det säkerställas att blåsan är tömd innan passage av bandet påbörjas på den andra sidan. Postoperativ kateterisering med kvarkateter är normalt inte nödvändigt. Patienten bör uppmanas att försöka tömma blåsan 2–3 timmar efter operationen.

KONTRAINDIKATIONER

Liksom för andra suspensionsoperationer gäller att detta ingrepp ej skall utföras på gravida. Eftersom PROLENE polypropylenänt inte täjns ut i någon nämnvärd grad skall ingreppet ej utföras på patienter som fortfarande växer eller kvinnor som planerar framtida graviditet.

VARNINGAR OCH FÖRSIKTIGHETSÅTGÄRDER

- Behandling med GYNECARE TVT obturatoriband får ej användas till patienter som står på antikoagulantia.
- GYNECARE TVT obturatoriband får ej användas till patienter med pågående urinvägsinfektion.
- Användaren skall vara förtrogen med den kirurgiska teknik som används vid suspension av uretra och skall ha erhållit adekvat utbildning i ingrepp med GYNECARE TVT obturatoriband innan GYNECARE TVT obturatoriband tas i bruk.
- Accepterad kirurgisk praxis skall följas vid ingreppet med GYNECARE TVT obturatoriband, liksom vid behandling av kontaminerade eller infekterade sår.
- Vid ingrepp med GYNECARE TVT obturatoriband skall försiktighet iaktas så att skador på stora kärl, nerver, blåsa och tarm undviks. Hänsynstagande till patientens anatomi och korrekt framföring av bandet bidrar till att minimera riskerna.
- Blödning kan förekomma postoperativt. Undersök om symptom eller tecken på blödning föreligger innan patienten skrivs ut från sjukhuset.
- Även om det är mindre sannolikt att blåsskador uppstår vid användning av denna teknik kan cystoskopi utföras, efter kirurgens bedömning.
- Plasthöljerna får inte avlägsnas förrän bandet har placerats i korrekt läge.
- Säkerställ att bandet är placerat med minimal spänning under uretras mellersta del.
- Om det kan befaras att operationsområdet är infekterat eller kontaminerat får detta ingrepp ej utföras.
- Eftersom ingen klinisk information för närvarande föreligger avseende graviditet efter suburetral slingplastik med GYNECARE TVT obturatoribandsystem skall patienten informeras om att framtida graviditeter kan omintetgöra effekten av den kirurgiska behandlingen och att patienten då åter kan bli inkontinent.
- Eftersom ingen klinisk information för närvarande föreligger avseende vaginal förlossning efter suburetral

slyngplastik med GYNECARE TVT obturatoriabandsystem skall förlösning via kejsarsnitt övervägas om patienten blir gravid.

- Efter operationen skall patienten instrueras om att avhålla sig från tunga lyft och/eller motion (t.ex. cykling, jogging) i minst tre till fyra veckor samt avstå från samlag under en månad postoperativt. Patienten kan vanligen återgå till övriga normala aktiviteter efter en eller två veckor.
- Patienten skall instrueras att omgående kontakta läkaren om dysuri, blödning eller andra problem uppstår.
- Övergående bensmärter som varar i 24–48 timmar kan förekomma och kan vanligen behandlas med lätta analgetika.
- Liksom vid andra inkontinensoperationer kan nyttillkommen detrusorinstabilitet förekomma efter suburetral slyngplastik med GYNECARE TVT obturatoriabandsystem. För att minimera denna risk skall bandet placeras enligt ovanstående beskrivning.
- PROLENE-nätet får inte komma i kontakt med suturklamrar, clips eller klämmare, eftersom mekaniska skador på nätet kan uppstå.
- GYNECARE TVT obturatoriaband och tillhörande komponenter får ej resteriliseras. Kassera oanvända produkter vars förpackningar har öppnats.
- Profylaktisk antibiotikabehandling kan tillämpas enligt kirurgens sedvanliga praxis.

BIVERKNINGAR

- Punktion eller laceration av blodkärl, nerver, urinblåsa, uretra eller tarm kan förekomma i samband med nålpassagen och kan kräva kirurgisk reparation.
- Övergående lokal irritation kring såren och övergående främmandekroppsreaktion kan förekomma. Denna reaktion kan resultera i utstötning, erosion, fistelbildning och inflammation.
- Som vid med alla främmande kroppar, kan PROLENE-nätet förvärra en befintlig infektion. Plasthöljerna som initialt täcker PROLENE-nätet under ingreppet är utformade för att minimera risken för kontaminering.
- Överkorrektion, dvs. om bandet spänns för hårt, kan leda till övergående eller permanent obstruktion av de nedre urinvägarna.

EGENSKAPER

Djurstudier visar att implantation av PROLENE-nät orsakar en minimal inflammatorisk vävnadsreaktion, som är övergående och följs av deponering av ett tunt bindvävslager som kan växa igenom nätmaskorna och på så sätt införliva nätet med intilliggande vävnad. Materialet resorberas inte och bryts inte heller ned eller försvagas av vävnadsenzymer.

LEVERANS

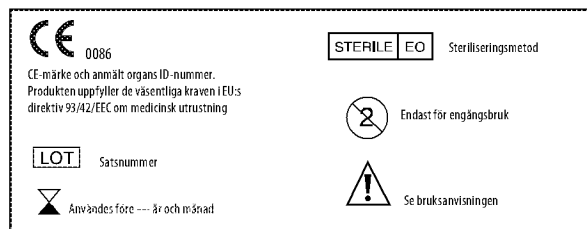
GYNECARE TVT obturatoriabandsystem levereras sterilt (etylenoxid), för engångsbruk. Får ej resteriliseras. Återanvändning av anordningen (eller delar av den) kan orsaka en degradering av produkten och kontamination vilket kan leda till infektioner eller överföring av blodburna patogener till patienter och användare. Produkten får ej användas om förpackningen varit öppnad tidigare eller är skadad. Kassera oanvända produkter vars förpackningar har öppnats.

FÖRVARING

GYNECARE TVT obturatoriabandsystem för engångsbruk bör förvaras vid temperatur under 25 °C och skyddas mot fukt och direkt värme. Får ej användas efter utgångsdatum.

OBS! Enligt amerikansk federal lagstiftning får denna anordning endast säljas av eller på order av läkare.

SYMBOLER ANVÄNDA VID MÄRKNING



ΕΛΛΗΝΙΚΑ

Σύστημα επιπωματικού **GYNECARE TVT™**

Σύστημα υποστήριξης για την αντιμετώπιση της ακράτειας, χωρίς τάση

Στείρα συσκευή επιπωματικού

GYNECARE TVT, μίας χρήσης

Στείροι ελικοειδείς εισαγωγείς επιπωματικού

GYNECARE TVT, μίας χρήσης

Στείρος ατραυματικός πτερυγωτός οδηγός επιπωματικού

GYNECARE TVT, μίας χρήσης

Διαβάστε προσεκτικά όλες τις πληροφορίες.

Εάν δεν ακολουθήσετε σωστά τις οδηγίες, η συσκευή πιθανόν να μη λειτουργήσει σωστά και ενδέχεται να προκληθεί τραυματισμός.

Σημαντικό:

Το παρόν ένθετο συσκευασίας έχει σχεδιαστεί για να παρέχει οδηγίες για τη χρήση του συστήματος επιπωματικού GYNECARE TVT™, στο οποίο συγκατατίθενται η συσκευή επιπωματικού, οι ελικοειδείς εισαγωγείς και ο ατραυματικός πτερυγωτός οδηγός GYNECARE TVT. Δεν αποτελεί ολοκληρωμένο οδηγό αναφοράς για χειρουργικές τεχνικές αποκατάστασης της ακράτειας ούρων από προσδόχεια (SUI). Η συσκευή θα πρέπει να χρησιμοποιείται αποκλειστικά από ιατρούς εκπαιδευμένους στη χειρουργική αντιμετώπιση της ακράτειας ούρων από προσδόχεια και ειδικότερα στην εμφύτευση της συσκευής επιπωματικού GYNECARE TVT. Αυτές οι οδηγίες προορίζονται για γενικές χρήσεις της συσκευής. Ενδέχεται να εφαρμοστούν παραλλαγές στη χρήση σε συγκεκριμένες περιπτώσεις, λόγω της χρησιμοποίησης τεχνικής και της ανατομίας της εκάστοτε ασθενούς.

ΠΕΡΙΓΡΑΦΗ

Το σύστημα επιπωματικού GYNECARE TVT είναι ένα στείρο κιτ επέμβασης για χρήση σε μια μόνον ασθενή, το οποίο αποτελείται από:

Συσκευή επιπωματικού GYNECARE TVT

Η συσκευή επιπωματικού GYNECARE TVT είναι μια στείρα συσκευή για χρήση σε μία μόνον ασθενή, η οποία αποτελείται από ένα τεμάχιο σχήματος ή μολε (μυϊκό φθάλαιοκωνικής, αριθμός χρωματικού δείκτη 74169) δικτυωτού πλέγματος PROLENE™ από πολυπροπυλένιο (ταυτό), διαστάσεων περίπου 1,1 cm x 45 cm, το οποίο καλύπτεται από ένα πλαστικό θηκάρι δύο τμημάτων που αλληλοεπικαλύπτονται στη μέση. Σε κάθε άκρο της συσκευής είναι προσαρμοσμένα πλαστικά σπληνάρια υποδοχής. Το πλέγμα πολυπροπυλενίου PROLENE κατασκευάζεται από ηλεκτά νήματα εξωθημένου πολυπροπυλενίου, πανομοιότυπου σε σύνθεση με εκείνο που χρησιμοποιείται στα μη απορροφήσιμα χειρουργικά νήματα πολυπροπυλενίου PROLENE. Το υλικό αυτό, όταν χρησιμοποιείται ως ράμμα, έχει αναφερθεί ότι είναι μη δραστήριο και ότι διατηρεί την αντοχή του εκ' άφροντος κατά την κλινική χρήση. Το δικτυωτό πλέγμα PROLENE σκέπεται με μια διαγράμμιση που συνδέει μεταξύ τους τις ενώσεις των νήων, εξασφαλίζοντας έτσι την ελαστικότητα και προς τις δύο κατευθύνσεις. Αυτή η ελαστικότητα προς δύο κατευθύνσεις επιτρέπει την προσαρμογή του στις διάφορες τάσεις που παρουσιάζονται στο σώμα.

Ελικοειδείς εισαγωγείς GYNECARE TVT

Οι ελικοειδείς εισαγωγείς GYNECARE TVT είναι δύο εισαγωγείς κυρτού σχήματος από ανοξείδωτο χάλυβα με πλαστικές λαβές, οι οποίες προορίζονται για την εμφύτευση της συσκευής επιπωματικού GYNECARE TVT. Οι ελικοειδείς εισαγωγείς παρέχονται ως αριστερή και δεξιά μονάδα, προσαρμοσμένα στην συσκευή επιπωματικού GYNECARE TVT. Ο ελικοειδής εισαγωγέας ΔΕΝ πρέπει να καμφθεί ή να παραμορφωθεί κατά οποιονδήποτε τρόπο.

Ατραυματικός πτερυγωτός οδηγός GYNECARE TVT

Ο ατραυματικός πτερυγωτός οδηγός GYNECARE TVT είναι ένα βοηθητικό εξάρτημα από ανοξείδωτο χάλυβα, το οποίο διευκολύνει τη διέδο των ελικοειδών εισαγωγέων GYNECARE TVT διαμέσου της οδού ανατομής.

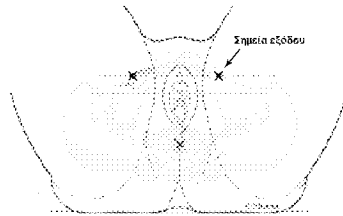
ΕΝΔΕΙΞΕΙΣ

Η συσκευή επιπωματικού GYNECARE TVT προορίζεται για χρήση σε γυναίκες, ως υπο-ουρηθρική σφενδύνη, για τη θεραπεία της ακράτειας ούρων από προσδόχεια (SUI), η οποία οφείλεται σε ουρηθρική υπερκινητικότητα και/ή εγγενή ανεπάρκεια του σφιγκτήρα.

ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ

(Σημείωση: Οι θέσεις των χεριών που φαίνονται στις εικόνες ενδέχεται να ποικίλουν.)

1. Τοποθετήστε την ασθενή σε ύπτια θέση λιθοτομής με τα ισχία σε υπέρκαμψη επάνω στην κοιλιακή χώρα. Οι γυυνοί θα πρέπει να τοποθετηθούν κατά μήκος του άκρου της τράπεζας.
2. Η επέμβαση μπορεί να γίνει υπό τοπική, περιφερική ή γενική αναισθησία.
3. Εάν είναι επιθυμητό, διονώζτε τα χείλη προκειμένου να επιτευχθεί μεγαλύτερη έκθεση.
4. Εισαγάγετε έναν ουρηθρικό καθετήρα στην ουροδόχο κύστη και εκκενώστε την.
5. Σημειώστε τα σημεία εξόδου των πλαστικών σπληνάρων, γνωρίζοντας μια οριζόντια γραμμή στο επίπεδο του ουρηθρικού σπληνίου και μια δεύτερη γραμμή παράλληλη με την πρώτη και 2 cm πάνω από αυτήν. Ψηφιάστε τα σημεία εξόδου επάνω σε αυτή τη γραμμή, 2 cm πλευρικά των πτυχών του μηρού (μπορείτε να εξομαλύνετε τα άκρα των νηώνων εάν το). Σημειώστε τα σημεία εξόδου ή, εναλλακτικά, κάντε μια τρύπα 5 mm-10 mm σε κάθε σημείο εξόδου σε μετρημένα σημεία της επέμβασης (βλέπε την εικόνα 1).

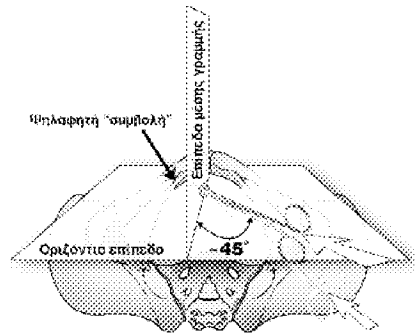


ΕΙΚΟΝΑ 1

6. Χρησιμοποιώντας σφυγκόμετρο Allis για την έλξη, κάντε μια τομή 1 cm στη μέση γραμμή του κοιλιακού βλενωγόνου, ξεκινώντας 1 cm αγγός του ομφαλικού σταθμού.

(Σημειώστε να ολοκληρωθεί η εισαγωγή της στήλης μιας πλευρά προτού ξεκινήσει η αντομή στη δεύτερη πλευρά.)

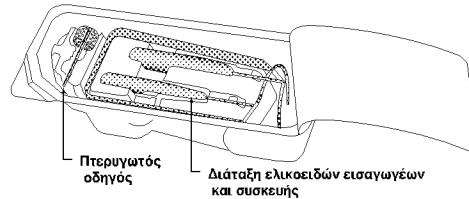
Μετά την αρχική τομή, εκτελέστε αμύδια αντομή με τεχνική "ώθησης-διάνοιξης" χρησιμοποιώντας, κατά προτίμηση, ένα μικρό, κυρτό ψαλίδι. Η πορεία της πλευρικής διατομής θα πρέπει να σχηματίζει γωνία 45° ως προς τη μέση γραμμή, με το ψαλίδι να βρίσκεται στο αρχικό επίπεδο (βλέπε την εικόνα 2). Συνεχίστε την αντομή προς την κατεύθυνση της αμύδιας μετά το σώματος του ηβικού οστού και του κατώτερου ηβικού κλάδου (βλέπε την εικόνα 2).



ΕΙΚΟΝΑ 2

Όταν φτάσετε στη συμβολή μεταξύ του σώματος του ηβικού οστού και του κατώτερου ηβικού κλάδου, διατηρήστε την επιφανειακή μεμβράνη. Μπορείτε να αισθανθείτε μείωση της αντίστασης όταν η μεμβράνη διασπαστεί. Το κανάλι πρέπει να έχει διάμετρο 5 mm-7 mm και βάθος 5 cm το πολύ. Η αντομή σε βάθος μεγαλύτερο από 5 cm ενδέχεται να προκαλέσει αιμορραγία στο χώρο μεταξύ του ηβικού οστού και της σφυροδόχου κύστης (χώρος Retzius). Εάν, μετά από αντομή 5 cm, δεν έχετε προσεγγίσει το στό, βεβαιωθείτε ότι η γωνία της αντομής είναι σωστή.

7. Αφαιρέστε τον σταθμό εργασίας της εσωτερικής ανασκευασίας από την εξωτερική ανασκευασία. Στη συνέχεια, αφαιρέστε τον πτερυγικό οδηγό SYNECARE TVT από το σταθμό εργασίας της ανασκευασίας (βλέπε την εικ.



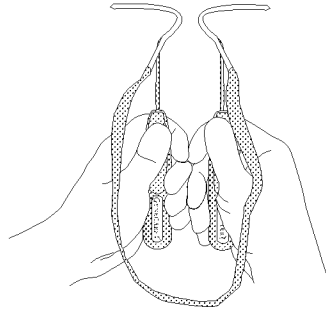
ΕΙΚΟΝΑ 3

8. Εισαγάγετε τον πτερυγικό οδηγό SYNECARE TVT μέσα στην οδό της αντομής, μέχρις ότου περάσει τον κατώτερο ηβικό κλάδο και εισέλθει στο άνοιγμα που έχει ήδη δημιουργηθεί στην επιφανειακή μεμβράνη. Μπορείτε να αισθανθείτε μείωση της αντίστασης καθώς ο πτερυγικός οδηγός περνά διαμέσου της επιφανειακής μεμβράνης. Εάν συναντήσετε δυσκολία κατά την είσοδο του οδηγού, επιβεβαιώστε την κατεύθυνση του καναλιού χρησιμοποιώντας το ψαλίδι.

(Σημείωση: Η ανοικτή πλευρά του οδηγού πρέπει να είναι στραμμένη προς τον χειρουργό. Η εύκαμπτη γλωττίδα μπορεί να καμφθεί για να αυξηθεί το μήκος του οδηγού, εάν αυτό απαιτείται - δεικνύεται στην εικόνα 5.)

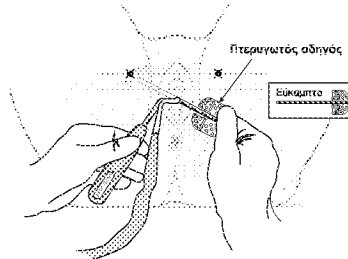
9. Αφαιρέστε τη διάταξη των ελικοειδών εισαγωγών και της συσκευής GYNECARE TVT και τη διάταξη της συσκευής επιπλωματικού GYNECARE TVT από τη στείρα συσκευασία (δείτε την εικ.).

(Σημείωση: Για να εξασφαλίσετε το σωστό προσανατολισμό των ελικοειδών εισαγωγών και της ταινίας, βεβαιωθείτε ότι το λογότυπο της GYNECARE και η εσοχή του δακτύλου επάνω στην πλαστική λαβή είναι στραμμένα προς τον χειρουργό, και ότι τα άκρα βρίσκονται στο εξωτερικό, στραμμένα προς τον χειρουργό. Ο ελικοειδής εισαγωγός που κρατά ο χειρουργός στο αριστό χέρι πρέπει να χρησιμοποιηθεί στη δεξιά πλευρά της σκελετούς - δ. την εικόνα 4.)



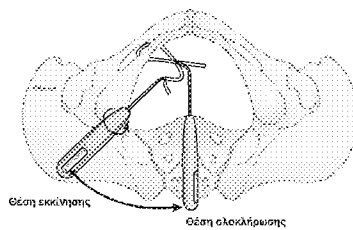
ΕΙΚΟΝΑ 4

10. Τοποθετήστε έναν από τους ελικοειδείς εισαγωγείς επάνω στα στείρα ιμάτια ή σε άλλη κατάλληλη στείρα θέση μέχρις ότου χρειαστεί. Βεβαιωθείτε ότι η ταινία δεν έχει συστραφεί.
11. Εισαγάγετε τον σωστό ελικοειδή εισαγωγέα GYNECARE TVT στην οδό της αναστομής, ακολουθώντας το κανάλι του περινεύματος οδηγού GYNECARE TVT. Βεβαιωθείτε ότι η λαβή της συσκευής είναι έτσι προσανατολισμένη ώστε το ευθύ άκρο του ελικοειδούς εισαγωγέα να είναι ευθυγραμμισμένο με το κανάλι του περινεύματος οδηγού GYNECARE TVT, και ότι διατηρεί τον προσανατολισμό αυτό μέχρις ότου το άκρο διασχίσει την επιπλωματική μεμβράνη (δείτε την εικόνα 5).



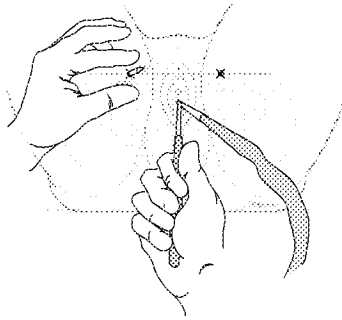
ΕΙΚΟΝΑ 5

12. Μόλις φτάσει στη θέση αυτή, αφαιρέστε τον περινεύμα οδηγό GYNECARE TVT και κρατήστε τον στείρο για περαιτέρω χρήση στην ίδια ασθενή.



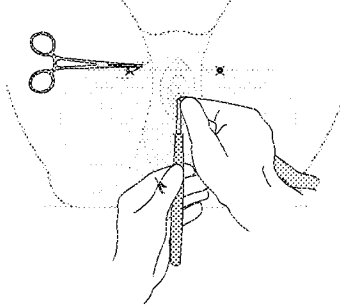
ΕΙΚΟΝΑ 6

13. Αφού αφαιρέσετε τον περινεύμα οδηγό GYNECARE TVT, περιστρέψτε τη λαβή του ελικοειδούς εισαγωγέα ενώ παράλληλα μετακινείτε τη λαβή προς τη μέση γραμμή, μέχρις ότου φτάσει σε θέση κάθετη προς το έδαφος (δείτε την εικ.). **(Σημείωση: Μην αφήσετε ποτέ τη λαβή να έρθει σε αριζόν**



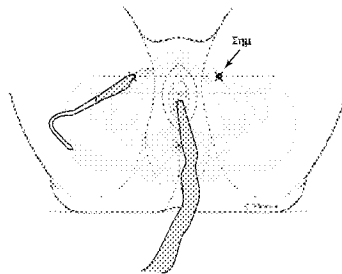
EIKONA 7

14. Το άκρο του ελαστικού εισαγωγέα θα πρέπει να εφλάθει κοντά στα προκαθορισμένα σημεία εφύδου (βλέπε την εικ. 7). Ωστόσο, ενδέχεται να χρειαστεί ελαφρός χειρισμός του δέρματος. Εάν δεν γίνει προηγουμένως τομή στο δέρμα, κάντε την τώρα στο σημείο όπου το άκρο του ελαστικού εισαγωγέα πιέζει το δέρμα. Όταν στο άνοιγμα του δέρματος φανεί το άκρο του πλαστικού σωληναρίου, συλλάβετε το μητερό άκρο του πλαστικού σωληναρίου με έναν σφιγκτήρα και, ενώ σταθεροποιείτε το σωληνάριο κοντά στην ουρήθρα με τον αντίχειρά σας, αφαιρέστε τον ελαστικό εισαγωγέα περιστρέφοντας αντίστροφα τη λαβή (βλέπε την εικόνα 8).



EIKONA 8

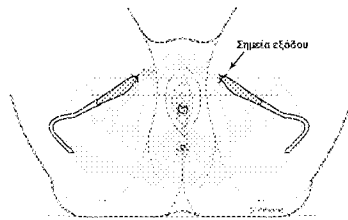
15. Ώξτε το πλαστικό σωληνάριο τελείως διαμέσου του δέρματος, μέχρις ότου εμφανιστεί η ταινία (βλέπε την εικ. 9).



EIKONA 9

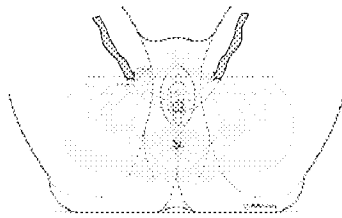
16. Επαναλάβετε την τεχνική στην άλλη πλευρά της ασθενούς, φροντίζοντας ώστε η ταινία να βρίσκεται επιπλέον κάτω από την ουρήθρα (βλέπε την εικόνα 10).

Σημείωση: Εάν όλα τα παραπάνω έχουν περυνωθετε ότι η περιστροφή αυτή δεν βρίσκειται κάτω από την ουρήθρα μετά τη διέλευση της περώσεως της ταινίας.)



ΕΙΚΟΝΑ 10

17. Όταν και τα δύο πλαστικά σωληνάκια έχουν εξέλθει διαμέσου των τομών στο δέρμα, κόψτε τα πλαστικά σωληνάκια από την ταινία και τα πλαστικά θηκάρια. Τοποθετήστε την ταινία χαλαρά (χωρίς τάση) και επίπεδη κάτω από τη μέση ουρήθρας. Σε αυτό το στάδιο μπορείτε να εκτελέσετε έναν έλεγχο με βήχα. Αυτό θα σας επιτρέψει να ρυθμίσετε την ταινία έτσι ώστε κατά τη διάρκεια του βήχα να διαφεύγουν μόνον λίγες σταγόνες ούρων (δείτε την εικόνα 11).



ΕΙΚΟΝΑ 11

Όταν η ταινία τοποθετηθεί στη σωστή θέση, αφαιρέστε το πλαστικό θηκάρι που καλύπτει τις ταινίες. Για να αποφύγετε την τοποθέτηση της ταινίας υπό τάση, τοποθετήστε ένα αμβλύ εργαλείο (π.χ. ψαλίδι ή λαβίδα) μεταξύ της ουρήθρας και της ταινίας κατά την αφαίρεση των πλαστικών θηκάρων, ή χρησιμοποιήστε άλλο κατάλληλο μέσο κατά την αφαίρεση των θηκάρων.

(Σημείωση: Η πρόωγη αφαίρεση του θηκαρίου ενδέχεται να ις επακόλουθες ρυθμίσεις.)

18. Μετά από τη ρύθμιση της ταινίας, κλείστε την κολλητική τομή. Κόψτε τα άκρα της ταινίας στα σημεία εξόδου, ακριβώς κάτω από το δέρμα του εσωτερικού μηρού. Κλείστε τις τομές του δέρματος με ράμμα ή με χειρουργικό συγκολλητικό δέρματος.
19. Η διενέργεια ή όχι κυστεοσκόπησης επαφίεται στην κρίση του χειρουργού. Εάν εκτελέστηκε κυστεοσκόπηση μετά το πέρας της ουσκευής από τη μια πλευρά, βεβαιωθείτε ότι η κύστη έχει εκκενωθεί προτού ξεκινήσετε το πέρας της ουσκευής στη δεύτερη πλευρά. Μετεγχειρητικά, δεν απαιτείται συνήθως η τοποθέτηση μόνιμου εσωτερικού καθετήρα. Θα πρέπει να ενθαρρύνετε την ασθενή να δοκιμάσει να κενώσει την κύστη της 2-3 ώρες μετά από την επέμβαση.

ΑΝΤΕΝΔΕΙΞΕΙΣ

Όπως συμβαίνει με όλες τις επεμβάσεις ανάρτησης, η επέμβαση αυτή δεν θα πρέπει να εκτελείται σε έγκυες ασθενείς. Επιπλέον, καθώς το πλέγμα πολυπροπυλενίου PROLINE δεν μπορεί να διασπαστεί σε σημαντικό βαθμό, δεν θα πρέπει να εφαρμόζεται σε ασθενείς που είναι πιθανόν να αναπτυχθούν, συμπεριλαμβανομένων των γυναικών που σχεδιάζουν μελλοντική εγκυμοσύνη.

ΠΡΟΕΙΔΟΠΟΙΗΣΕΙΣ ΚΑΙ ΠΡΟΦΥΛΑΞΕΙΣ

- Μην χρησιμοποιείτε την επέμβαση επιπωματικού GYNECARE TVT σε ασθενείς οι οποίες ακολουθούν αντιπηκτική θεραπεία.
- Μην εκτελείτε την επέμβαση επιπωματικού GYNECARE TVT σε ασθενείς με ουρολοιμώδη.
- Πριν από τη χρήση της ουσκευής επιπωματικού GYNECARE TVT, οι χρήστες θα πρέπει να είναι εξοικειωμένοι με τη χειρουργική τεχνική ανάρτησης της ουρήθρας και θα πρέπει να είναι επαρκώς εκπαιδευμένοι στην επέμβαση επιπωματικού GYNECARE TVT.
- Για την επέμβαση επιπωματικού GYNECARE TVT, όπως και για τη θεραπεία ρολοισμένων ή επιμολυσμένων τραυμάτων, ακολουθήστε τις γενικά αποδεκτές χειρουργικές πρακτικές.
- Η επέμβαση επιπωματικού GYNECARE TVT θα πρέπει να εκτελείται με προσοχή ώστε να αποφεύγονται τα μεγάλα αγγεία, τα νεύρα, η κύστη και το έντερο. Οι κίνδυνοι ελαχιστοποιούνται εάν δοθεί προσοχή στην ανατομία της ασθενούς και στη σωστή διάθεση της ουσκευής.
- Ενδέχεται να εμφανιστεί αιμορραγία μετεγχειρητικά. Εξετάστε την ασθενή για οποιαδήποτε συμπτώματα ή σημεία πριν από την έξοδό της από το νοσοκομείο.
- Παρόλο που δεν είναι πιθανή η πρόκληση βλάβης στην κύστη κατά τη χρήση της τεχνικής αυτής, η διενέργεια ή όχι κυστεοσκόπησης επαφίεται στην κρίση του χειρουργού.
- Μην αφαιρέτε τα πλαστικά θηκάρια μέχρις ότου τοποθετηθεί σωστά η ταινία.
- Βεβαιωθείτε ότι η ταινία έχει τοποθετηθεί με την ελάχιστη τάση κάτω από τη μέση ουρήθρας.

- Μην εκτελείτε την επέμβαση εάν πιστεύετε ότι το σημείο της χειρουργικής επέμβασης ενδέχεται να έχει υποστεί λοίμωξη ή μόλυνση.
- Καθώς δεν υπάρχουν διαθέσιμες κλινικές πληροφορίες σε σχέση με την κύηση μετά από επέμβαση υπο-οδηγηθικής σφενδόνης με το σύστημα επιπωματικού GYNECARE TVT, η ασθενής θα πρέπει να ενημερωθεί για το γεγονός ότι τυχόν μελλοντική κύηση ενδέχεται να ανατρέπει το αποτέλεσμα της χειρουργικής επέμβασης, με συνέπεια να επανέλθει η ακράτεια.
- Καθώς δεν υπάρχουν διαθέσιμες κλινικές πληροφορίες σε σχέση με τον κοιλιακό τοκετό μετά από επέμβαση υπο-οδηγηθικής σφενδόνης με το σύστημα επιπωματικού GYNECARE TVT, σε περίπτωση εγκυμοσύνης θα πρέπει να εξεταστεί η δυνατότητα τοκετού μέσω καισαρικής τομής.
- Μετά από την επέμβαση, σιγανύεται στην ασθενή να αποφεύγει να σηκώνει βάρη κανή να ασκείται (π.χ. ποδηλασία, τρέξιμο) επί τρεις έως τέσσερις εβδομάδες τουλάχιστον και να μην έλθει σε σεξουαλική επαφή επί έναν μήνα. Οι περισσότερες ασθενείς μπορούν να επιστρέψουν στις άλλες συνήθειες δραστηριοτήτες μετά από μια ή δύο εβδομάδες.
- Πρέπει να ζητηθεί από την ασθενή να επικοινωνήσει άμεσα με τον χειρουργό εάν εμφανιστεί δυσουρία, αιματουρία ή άλλα προβλήματα.
- Ενδέχεται να εμφανιστεί παροδικό άλγος στα πόδια επί 24-48 ώρες, το οποίο συνήθως μπορεί να αντιμετωπιστεί με ήπια αναλγητικά.
- Όπως συμβαίνει και με άλλες επεμβάσεις για την αντιμετώπιση της ακράτειας, ενδέχεται να εμφανιστεί εκ νέου αστάθεια του εξωστήρα μυός μετά από την επέμβαση υπο-οδηγηθικής σφενδόνης με το σύστημα επιπωματικού GYNECARE TVT. Για να ελαχιστοποιήσει αυτόν τον κίνδυνο, βεβαιωθείτε ότι τοποθετήσατε την ταινία όπως περιγράφηκε ανωτέρω.
- Μην φέρετε σε επαφή το πλέγμα PROLENE με συνδετήρες, κλίπ ή σφιγκτήρες, καθώς ενδέχεται να προκληθεί μηχανική βλάβη στο πλέγμα.
- Μην επαναποστερώνετε τη συσκευή επιπωματικού GYNECARE TVT ή τα εξαρτήματά της. Απορρίψτε τις αποσυσκευασμένες, σχηματισμένες συσκευές.
- Μπορεί να χορηγηθεί προφυλακτική αντιβιοτική αγωγή σύμφωνα με τη συνήθη πρακτική του χειρουργού.

ΑΝΕΠΙΘΥΜΗΤΕΣ ΑΝΤΙΔΡΑΣΕΙΣ

- Κατά τη διάρκεια της βελόνας ενδέχεται να προκύψει διότρηση ή ρήξη αγγείων και νεύρων, καθώς και της κύστης ή του εντέρου, οι οποίες πιθανόν να απαιτήσουν χειρουργική αποκατάσταση.
- Είναι πιθανόν να εμφανιστεί παροδικός τοπικός ερεθισμός στο σημείο της πληγής και παροδική αντίδραση ξένου σώματος. Η αντίδραση αυτή μπορεί να οδηγήσει σε εξόθιση, διάβρωση, σχηματισμό σφηνόχυι ή φλεγμονή.
- Όπως συμβαίνει με όλα τα ξένα σώματα, το πλέγμα PROLENE ενδέχεται να εσχαώσει τυχόν υπάρχουσα λοίμωξη. Τα πλαστικά όργανα που καλύπτουν αρχικά το πλέγμα PROLENE είναι σχεδιασμένα έτσι ώστε να ελαχιστοποιούν τον κίνδυνο μόλυνσης.
- Η υπερβολική διότρηση, δηλαδή η εφαρμογή υπερβολικής τάσης στην ταινία, ενδέχεται να προκαλέσει προσωρινή ή μόνιμη ενόφθαλη της κατώτερης ουροφόρου οδού.

ΔΡΑΣΕΙΣ

Μελέτες σε ζώα υποδεικνύουν ότι η εμφύτευση του πλέγματος PROLENE προκαλεί ελάχιστη φλεγμονώδη αντίδραση στους ιστούς, η οποία είναι παροδική και ακολουθείται από την εναπόθεση μιας λεπτής ινώδους επίστρωσης από η οποία μπορεί να αναπτυχθεί διαμέσου των διακένων του πλέγματος, ενσωματώνοντας έτσι το πλέγμα στον παρόντιμα ιστό. Το υλικό δεν απορροφάται, ούτε υφίσταται αποδόμηση ή εξασθένηση από τη δράση των ενζύμων του ιστού.

ΤΡΟΠΟΣ ΔΙΑΘΕΣΗΣ

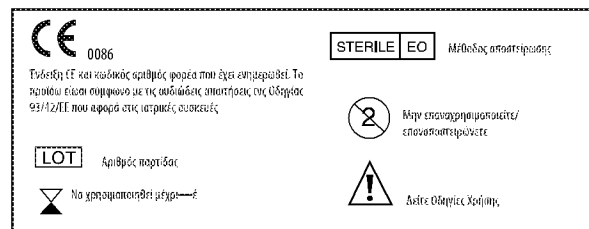
Το σύστημα επιπωματικού GYNECARE TVT παρέχεται στείρα (αξείδιο του αιθυλενίου) για μία μόνον χρήση. Μην το επαναποστερώνετε. Η επαναχρησιμοποίηση αυτής της συσκευής (ή μερών αυτής της συσκευής) είναι δυνατό να προκαλέσει κίνδυνο αποδόμησης του προϊόντος και διασπορεύουσας μόλυνσης, η οποία ενδέχεται να οδηγήσει σε λοίμωξη ή μετάδοση αιματογενώς μεταδιδόμενων παθογόνων μικροοργανισμών σε ασθενείς και χρήστες. Μην το χρησιμοποιείτε εάν η συσκευασία έχει ανοίξει ή έχει υποστεί ζημιά. Απορρίψτε τις αποσυσκευασμένες, σχηματισμένες συσκευές.

ΦΥΛΑΞΗ

Οι συνιστάμενες συνθήκες φύλαξης για τη συσκευή μιας χρήσης του συστήματος επιπωματικού GYNECARE TVT είναι οι εξής: θερμοκρασία χαμηλότερη των 25 °C, μακριά από υγρασία και άμεσες πηγές θερμότητας. Μην τη χρησιμοποιείτε μετά την παρέλευση της ημερομηνίας λήξης.

ΠΡΟΣΟΧΗ: Η ομοσπονδιακή νομοθεσία (H.D.A.) π ορίζει την πώληση της συσκευής αυτής μόνο σε παρούς ή κατόπιν εντολής ιατρού.

ΣΥΜΒΟΛΑ ΧΡΗΣΙΜΟΠΟΙΟΥΜΕΝΑ ΚΑΤΑ ΤΗΝ ΣΗΜΑΝΣΗ ΤΗΣ ΣΥΣΚΕΥΑΣΙΑΣ



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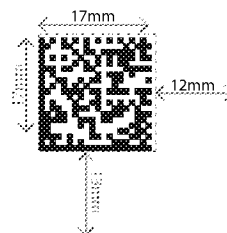


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Gynecare PROSIMA™

Anterior Pelvic Floor Repair System
Posterior Pelvic Floor Repair System
Combined Pelvic Floor Repair System

System til anterior støtte af bækkenbund
System til posterior støtte af bækkenbund
System til kombineret støtte af bækkenbund

Bekkenbodereparatiesysteem anterieur
Bekkenbodereparatiesysteem posterieur
Bekkenbodereparatiesysteem gecombineerd

Anteriorinen lantionpohjan korjausjärjestelmä
Posteriorinen lantionpohjan korjausjärjestelmä
Yhdistetty lantionpohjan korjausjärjestelmä

Système de réparation du plancher pelvien antérieur
Système de réparation du plancher pelvien postérieur
Système de réparation combiné du plancher pelvien

Anteriores Beckenboden-Rekonstruktionssystem
Posteriores Beckenboden-Rekonstruktionssystem
Kombiniertes Beckenboden-Rekonstruktionssystem

Sistema di riparazione anteriore del pavimento pelvico
Sistema di riparazione posteriore del pavimento pelvico
Sistema di riparazione combinato del pavimento pelvico

Sistema de Reparação do Pavimento Pélvico Anterior
Sistema de Reparação do Pavimento Pélvico Posterior
Sistema de Reparação do Pavimento Pélvico Combinado

Sistema de reparación del suelo pélvico anterior
Sistema de reparación del suelo pélvico posterior
Sistema de reparación del suelo pélvico combinado

System för reparation av främre delen av bäckenbotten
System för reparation av bakre delen av bäckenbotten
System för kombinerad reparation av bäckenbotten

Σύστημα αποκατάστασης πρόσθιου πυελικού εδάφους
Σύστημα αποκατάστασης οπίσθιου πυελικού εδάφους
Συνδυασμένο σύστημα αποκατάστασης πυελικού εδάφους



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EXHIBIT E

ETH.MESH.02341398

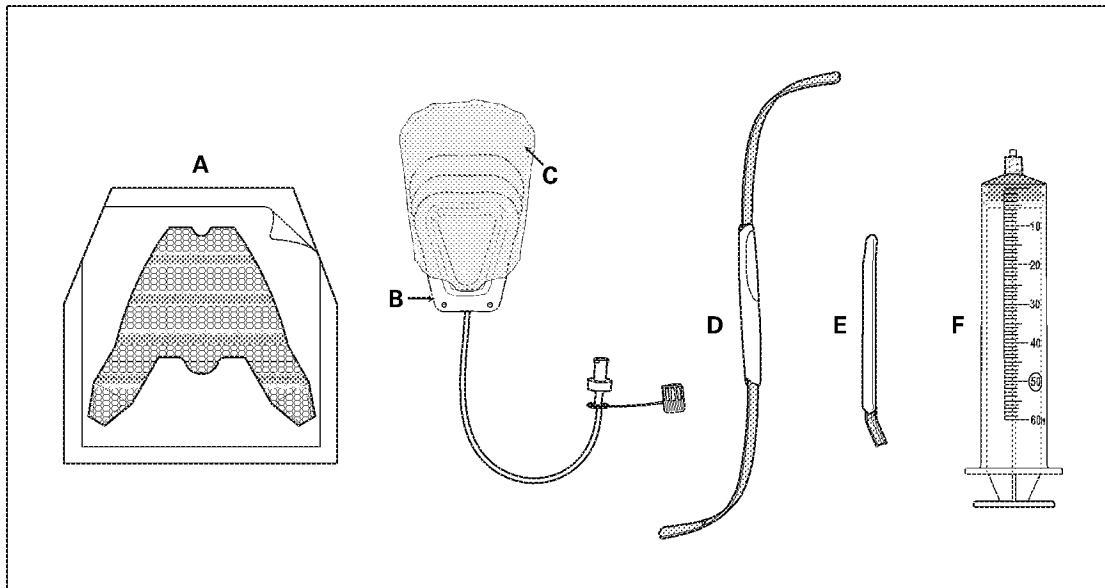


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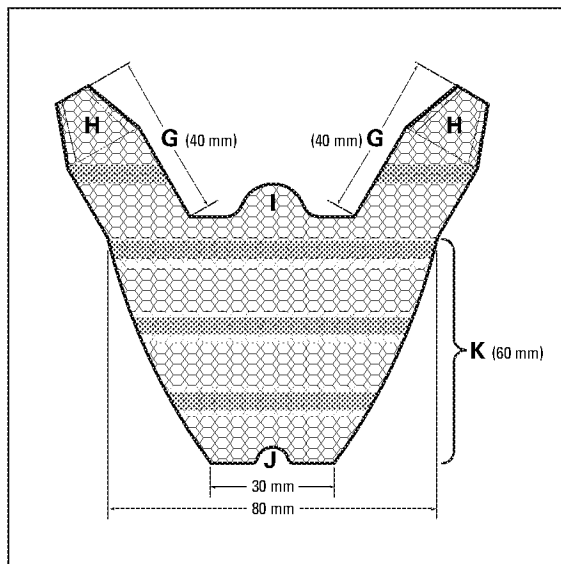


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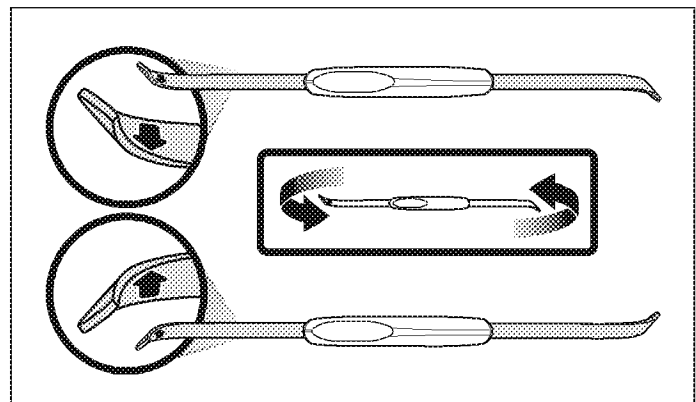


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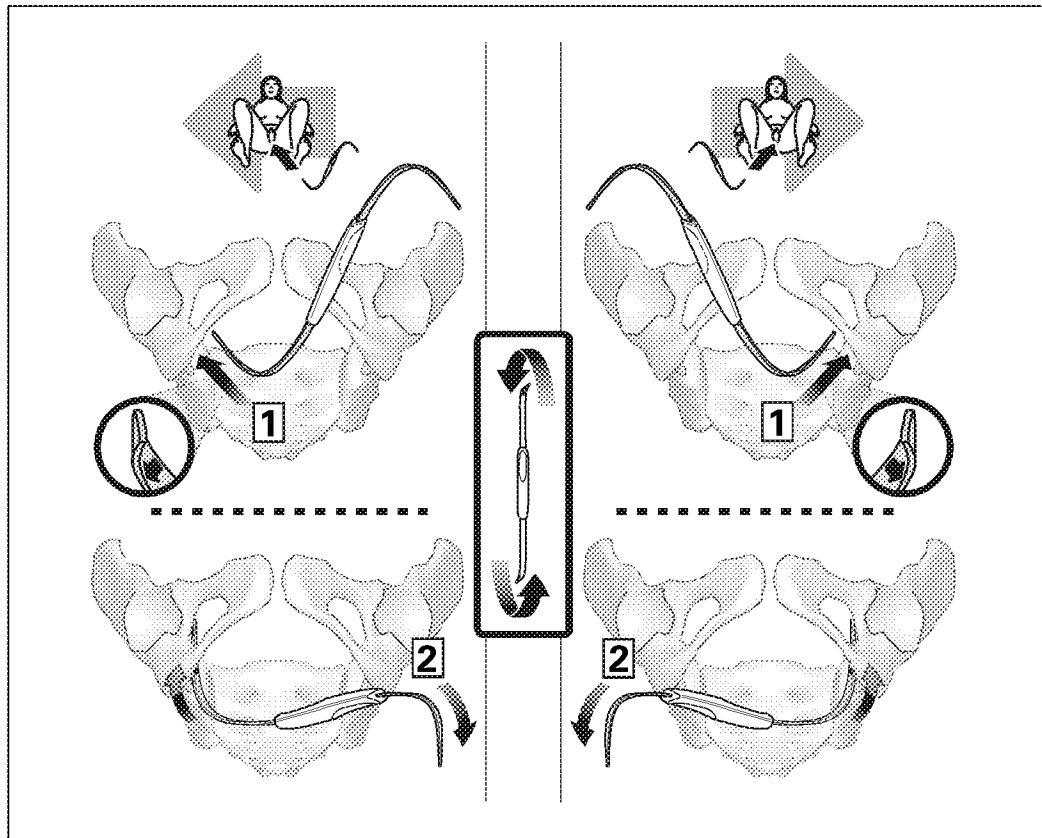


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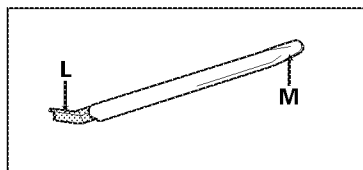


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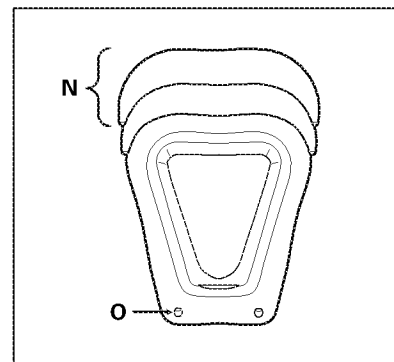


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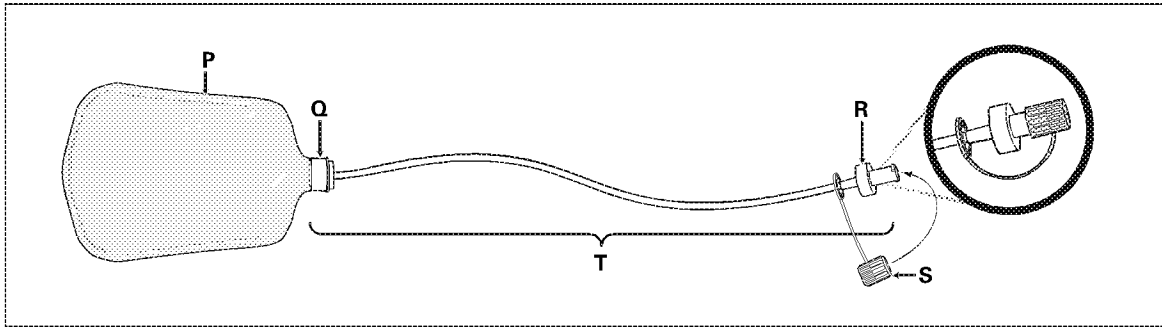


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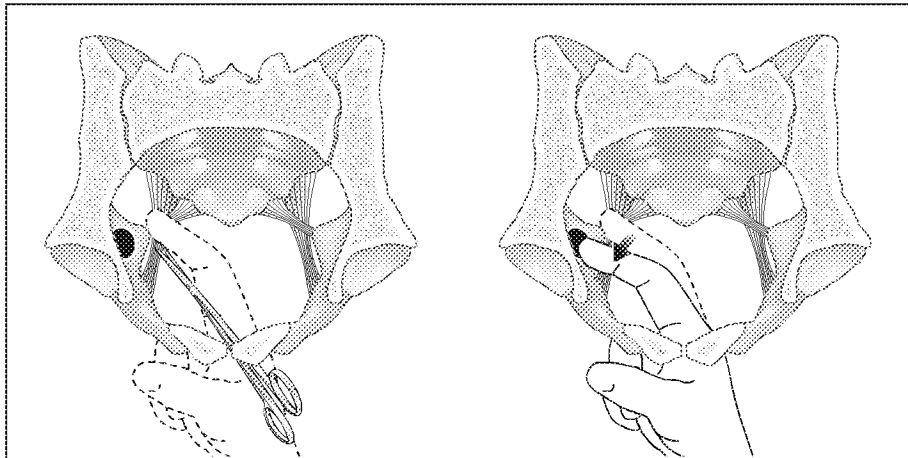


Figure 8A

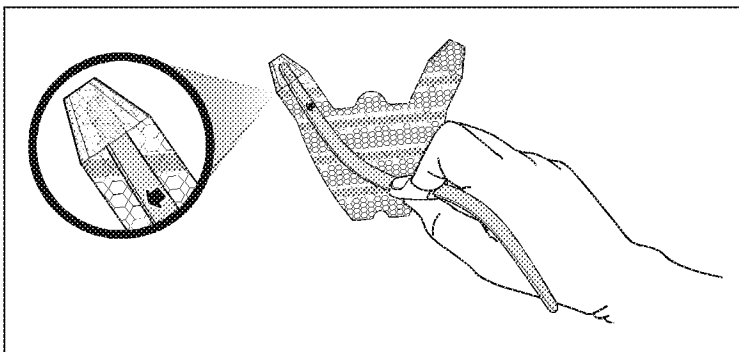


Figure 8B

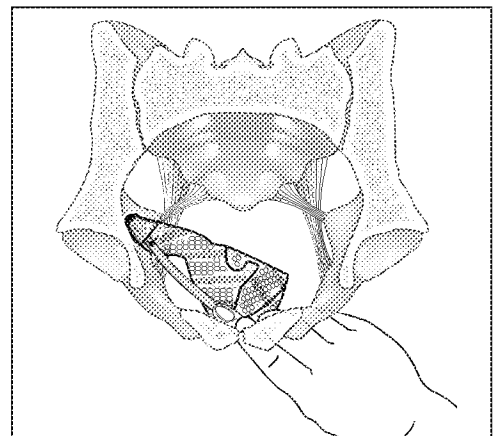


Figure 8C

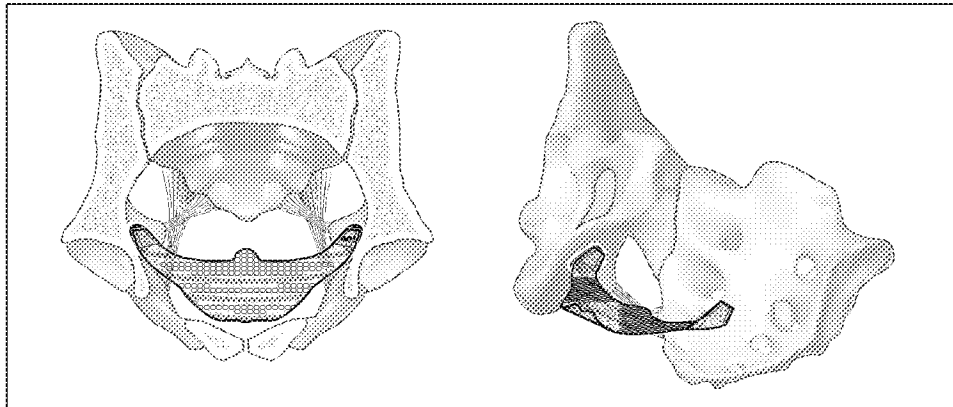


Figure 8D

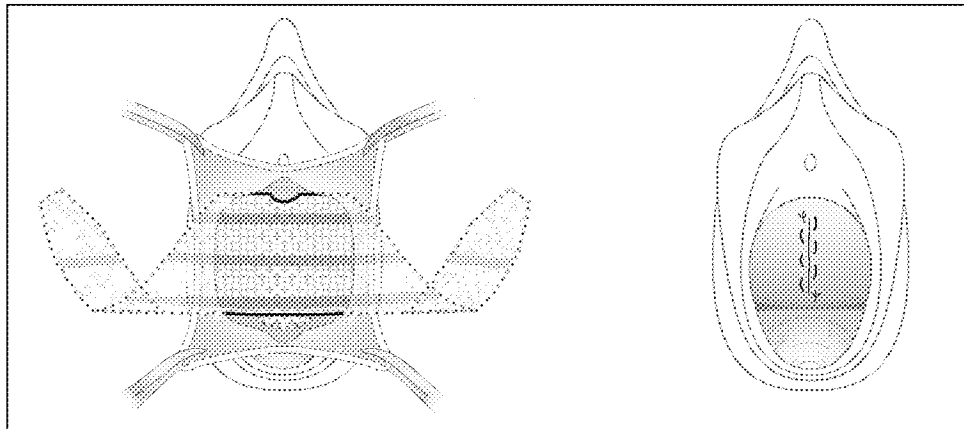


Figure 8E

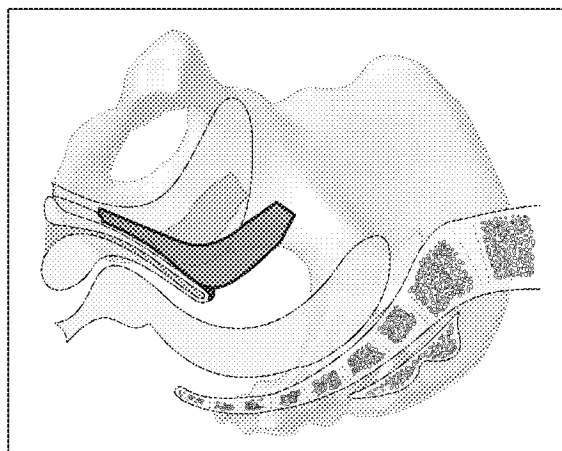


Figure 8F

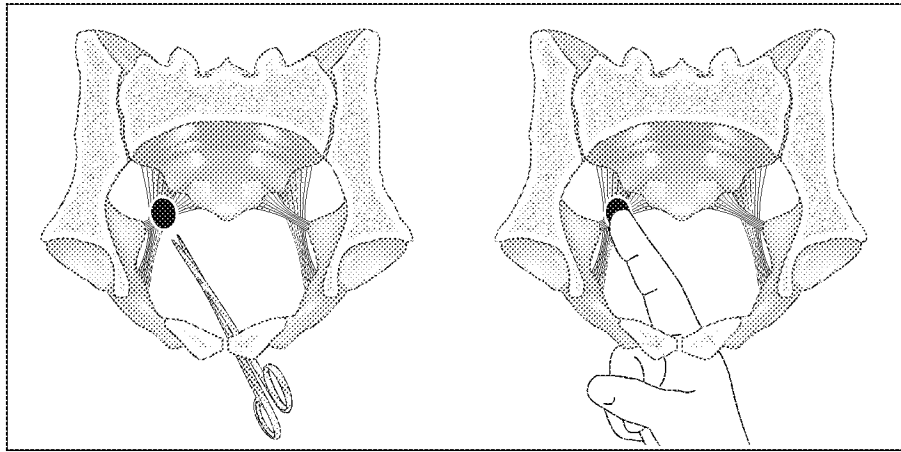


Figure 9A

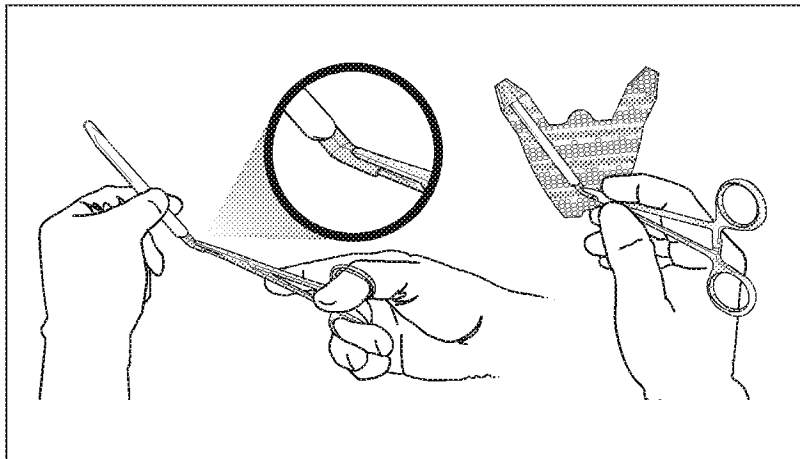


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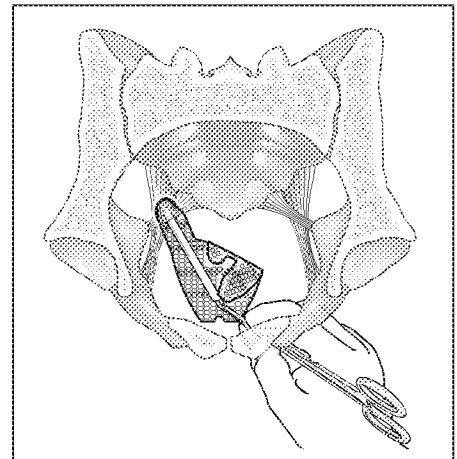


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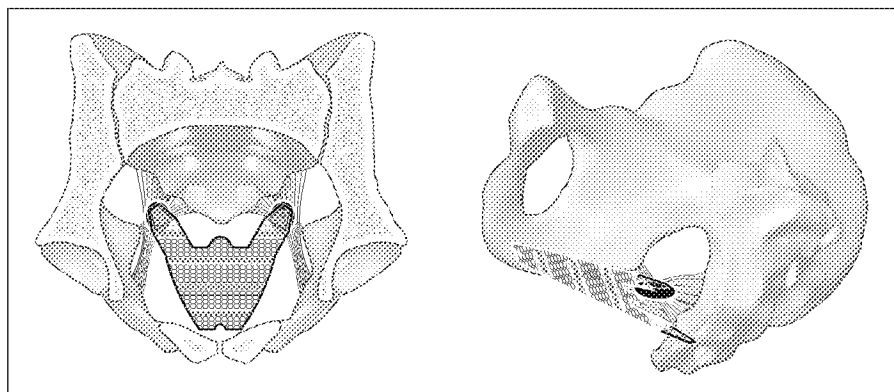


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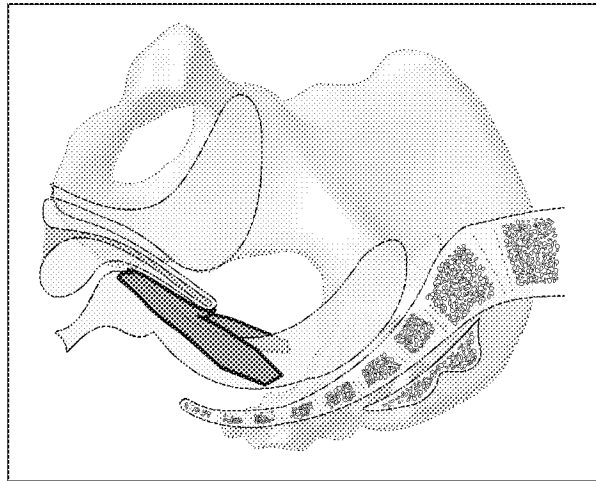


Figure 9E

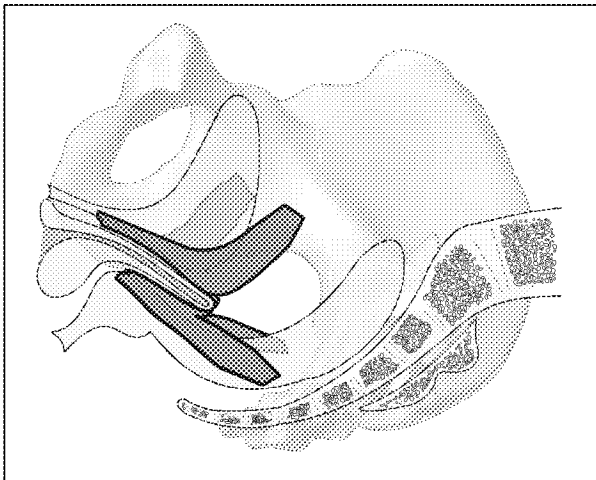


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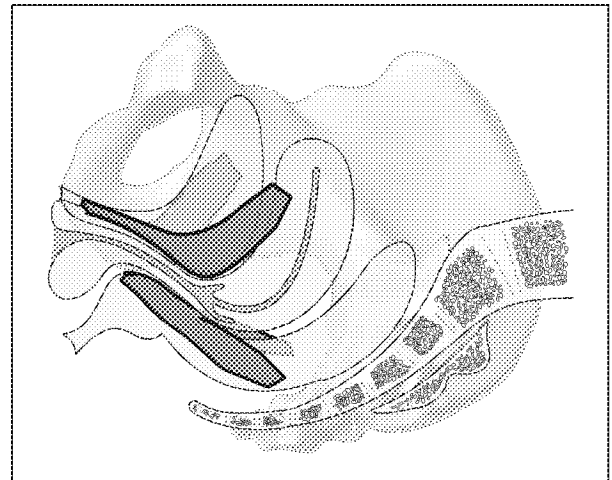


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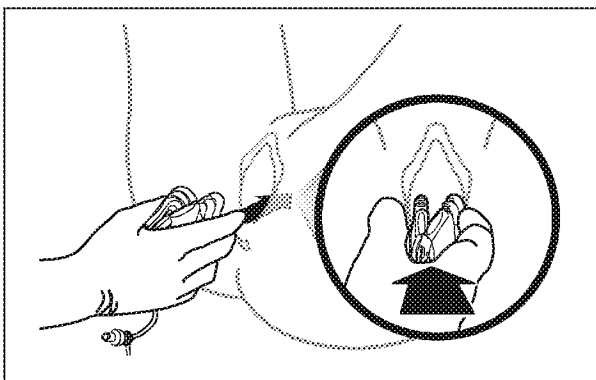


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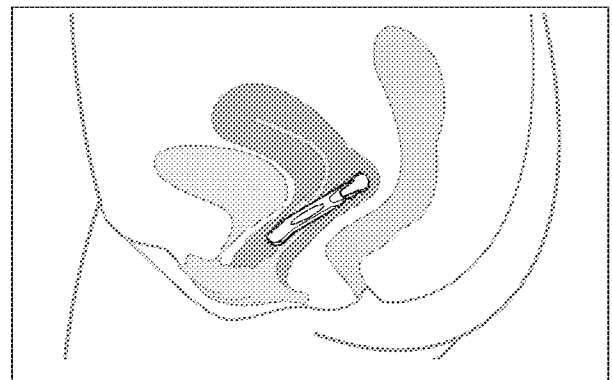


Figure 13

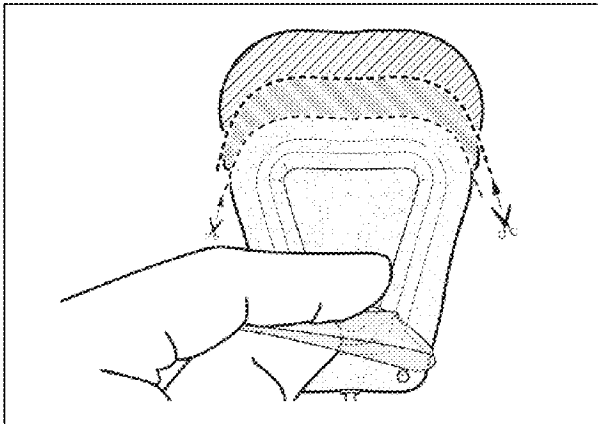


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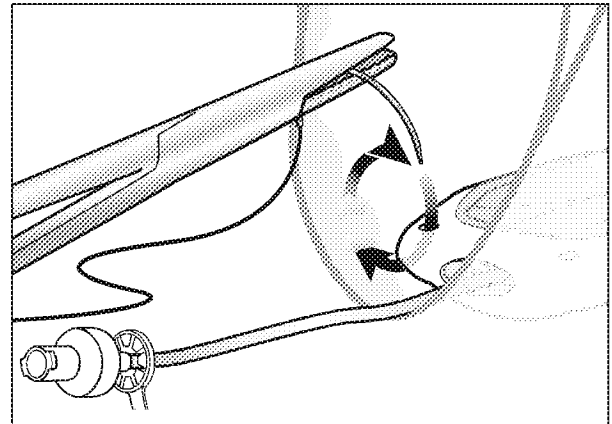


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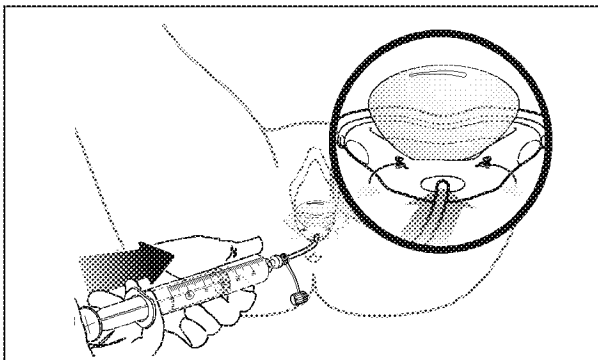


Figure 16

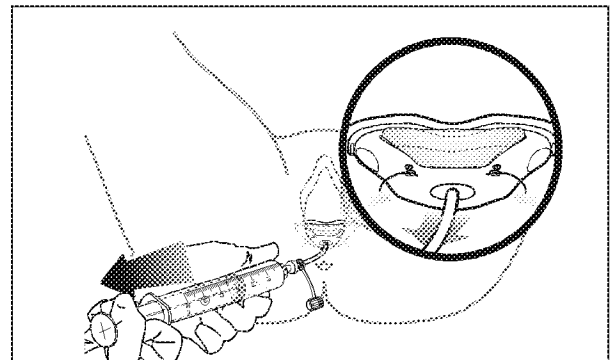


Figure 17

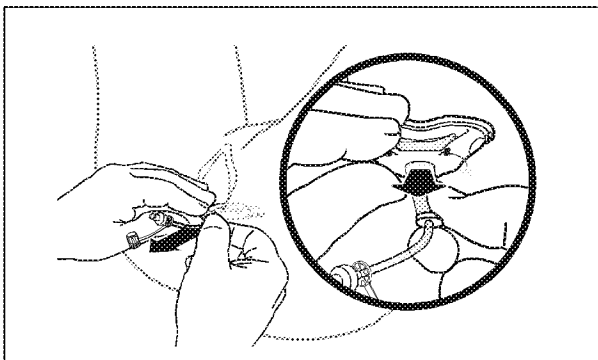


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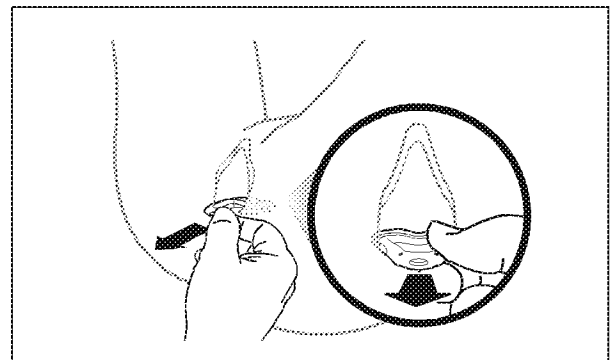


Figure 19

ENGLISH

A – Mesh Implant in Implant Carrier
 B – Vaginal Support Device (VSD)
 C – Balloon
 D – Anterior Insertor
 E – Posterior Insertor
 F – Syringe
 G – Straps of Mesh Implant
 H – Pockets of Mesh Implant
 I – Apical tab of Mesh Implant
 J – Distal groove of Mesh Implant
 K – Body of Mesh Implant
 L – Connection groove of Posterior Insertor
 M – Distal end of Posterior Insertor
 N – Trimable sections of VSD
 O – Suture eyelets of VSD
 P – Balloon
 Q – Connector plug of Balloon
 R – Valve of Balloon
 S – Cap of Balloon
 T – Inflation line of Balloon

DANSK

A – Meshimplantat i implantatemballe
 B – Vaginal støtteanordning (VSD – Vaginal Support Device)
 C – Ballon
 D – Anterior indfører
 E – Posterior indfører
 F – Sprøjte
 G – Meshimplantatstropper
 H – Meshimplantatlommer
 I – Apikal flig på meshimplantat
 J – Distal rille i meshimplantat
 K – Hovedpart af meshimplantat
 L – Forbindelsesrille på posterior indfører
 M – Distal ende af posterior indfører
 N – Justerbare sektioner af VSD
 O – Suturhuller i VSD
 P – Ballon
 Q – Forbindelsesstykke på ballon
 R – Ballonventil
 S – Ballonhætte
 T – Opustningsslange til ballon

NEDERLANDS

A – Meshimplantaat in implantaathouder
 B – VSD (Vaginal Support Device, vaginasteun)
 C – Ballon
 D – Inbrenginstrument anterieur
 E – Inbrenginstrument posterieur
 F – Spuit
 G – Bandjes van meshimplantaat
 H – Zakjes van meshimplantaat
 I – Apicaal lipje van meshimplantaat
 J – Distale groef van meshimplantaat
 K – Hoofddeelte van meshimplantaat
 L – Verbindingsgroef van posterieur inbrenginstrument
 M – Distaal uiteinde van posterieur inbrenginstrument
 N – Afknipbare delen van de VSD (vaginasteun)
 O – Hechtingsoogjes van de VSD
 P – Ballon
 Q – Ballonaansluitstuk
 R – Ballonafsluiter
 S – Ballondop
 T – Ballonvulling

SUOMI

A – Verkkoiimplantti implantinasettimessa
 B – Enäntintuki
 C – Pallo
 D – Anteriorinen sisäänviejä
 E – Posteriorinen sisäänviejä
 F – Ruisku
 G – Verkkoiimplantin nauhat
 H – Verkkoiimplantin taskut
 I – Verkkoiimplantin kärkikideleke
 J – Verkkoiimplantin distaalilovi
 K – Verkkoiimplantin runko
 L – Posteriorisen sisäänviejän liitinovi
 M – Posteriorisen sisäänviejän distaalipää
 N – Enäntintuen leikattavat osat
 O – Enäntintuen ommelreiät
 P – Pallo
 Q – Pallon liitin
 R – Pallon venttili
 S – Pallon korkki
 T – Pallon täyttöletku

FRANÇAIS

A – Prothèse dans son emballage
 B – Dispositif de Support Vaginal (DSV)
 C – Ballonnet
 D – Introducteur antérieur
 E – Introducteur postérieur
 F – Seringue
 G – Bras de la prothèse
 H – Poches de la prothèse
 I – Languette apicale de la prothèse
 J – Echanure distale de la prothèse
 K – Corps de la prothèse
 L – Gorge de connexion de l'introducteur postérieur
 M – Extrémité distale de l'introducteur postérieur
 N – Sections découpables du DSV
 O – Gilets de suture du DSV
 P – Ballonnet
 Q – Prise de connexion du ballonnet
 R – Valve du ballonnet
 S – Bouchon du ballonnet
 T – Tubulure de gonflage du ballonnet

DEUTSCH

A – Netziimplantat im Implantatträger
 B – Vaginal-Splint (Vaginal Support Device, VSD)
 C – Luftkissen
 D – Anteriores Einführinstrument
 E – Posteriores Einführinstrument
 F – Spritze
 G – Halteschlaufen des Netziimplantats
 H – Taschen des Netziimplantats
 I – Apikale Lasche des Netziimplantats
 J – Distale Kerbe des Netziimplantats
 K – Körper des Netziimplantats
 L – Verbindungsnille des posterioren Einführinstruments
 M – Distales Ende des posterioren Einführinstruments
 N – Zuschneidbare Anteile des VSD
 O – Nahtöffnungen des VSD
 P – Luftkissen
 Q – Anschlussstecker des Luftkissens
 R – Luftkissenventil
 S – Luftkissenkappe
 T – Luftschlauch des Luftkissens

ITALIANO

A – Implanto in rete nell'apposita confezione
 B – Dispositivo di supporto vaginale (DSV)
 C – Palloncino
 D – Introduuttore anteriore
 E – Introduuttore posteriore
 F – Siringa
 G – Braccia dell'implanto in rete
 H – Tasche dell'implanto in rete
 I – Linguetta apicale dell'implanto in rete
 J – Scanalatura distale dell'implanto in rete
 K – Corpo dell'implanto in rete
 L – Scanalatura di collegamento dell'introduuttore posteriore
 M – Estremità distale dell'introduuttore posteriore
 N – Sezioni sagomabili del DSV
 O – Occhielli per sutura del DSV
 P – Pallone
 Q – Palloncino
 R – Spinotto di collegamento del palloncino
 S – Valvola del palloncino
 T – Coperchio del palloncino
 U – Tubo d'insufflazione del palloncino

PORTUGUÊS

A – Implante de Rede na Embalagem de Transporte do Implante
 B – Dispositivo de Suporte Vaginal (VSD)
 C – Balão
 D – Introduutor Anterior
 E – Introduutor Posterior
 F – Seringa
 G – Tiras do Implante de Rede
 H – Bolsas do Implante de Rede
 I – Aba Apical do Implante de Rede
 J – Entalhe Distal do Implante de Rede
 K – Corpo do Implante de Rede
 L – Ranhura de Conexão do Introduutor Posterior
 M – Extremidade Distal do Introduutor Posterior
 N – Seções Recortáveis do VSD
 O – Orlões de Sutura do VSD
 P – Balão
 Q – Rolhão Conector do Balão
 R – Válvula do Balão
 S – Tampa do Balão
 T – Linha de Insuflação do Balão

ESPAÑOL

A – Implante de malla en el portaimplante
 B – Dispositivo de soporte vaginal (VSD)
 C – Balón
 D – Insertador anterior
 E – Insertador posterior
 F – Jeringa
 G – Tiras de implante de malla
 H – Bolsillos de implante de malla
 I – Lengüeta apical de implante de malla
 J – Surco distal del implante de malla
 K – Cuerpo del implante de malla
 L – Surco de conexión de insertador posterior
 M – Extremo distal del insertador posterior
 N – Secciones recortables de VSD
 O – Ojos de sutura del VSD
 P – Balón
 Q – Tapón conector del balón
 R – Válvula del balón
 S – Tapa del balón
 T – Línea de inflado de balón

SVENSKA

A – Nätimplantat i implantatshållare
 B – Vaginalstöd (VSD)
 C – Ballong
 D – Främre införare
 E – Bakre införare
 F – Injektionsspruta
 G – Remmar till nätimplantat
 H – Fickor på nätimplantat
 I – Apikal fläk på nätimplantat
 J – Distal skära på nätimplantat
 K – Nätimplantatets huvuddel
 L – Bakre införarens kopplingskära
 M – Bakre införarens distala ände
 N – Tillklippbara delar av VSD
 O – Suturehål på VSD
 P – Ballong
 Q – Kopplingsdon på ballongen
 R – Ventil på ballongen
 S – Lock till ballongen
 T – Fyllnads slang till ballongen

ΕΛΛΗΝΙΚΑ

A – Εμφύτευμα πλέγματος στο φάρμα εμφυτεύματος
 B – Διατεταχ Κολάση Υποστήριξης (ΔΚΥ)
 C – Μπαλόνι
 D – Επρόσθιος εισαγωγέας
 E – Οπίσθιος εισαγωγέας
 F – Σύριγγα
 G – Λιμένες του εμφυτεύματος πλέγματος
 H – Θάλασσα του εμφυτεύματος πλέγματος
 I – Κορυφαίο γλωττίδιο του εμφυτεύματος πλέγματος
 J – Περιφερική αύλακα του εμφυτεύματος πλέγματος
 K – Σώμα του εμφυτεύματος πλέγματος
 L – Αύλακα σύνδεσης του οπίσθιου εισαγωγέα
 M – Περιεκτώμενα τμήματα της ΔΚΥ
 N – Οπές σχηματισμού της ΔΚΥ
 P – Μπαλόνι
 Q – Βύσμα σύνδεσης του μπαλονιού
 R – Βαλβίδα του μπαλονιού
 S – Γώμιο του μπαλονιού
 T – Γραμμή διάτρησης του μπαλονιού



ENGLISH

Please read all information carefully.

Failure to properly follow instructions may result in improper functioning of the devices and lead to injury.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Training on the use of the GYNECARE PROSIMA™ Pelvic Floor Repair Systems is recommended and available. Contact your company sales representative to arrange for this training.

INDICATIONS

The GYNECARE PROSIMA Pelvic Floor Repair Systems, through the placement of GYNECARE GYNEMESH™ PS Nonabsorbable PROLENE™ Soft Mesh Implants, are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor, either as mechanical support or bridging material for the fascial defect. The Systems provide maintenance of the vaginal canal during the period of healing following surgical repair of vaginal wall prolapse, while supporting the position of the Mesh Implants.

DESCRIPTION

The GYNECARE PROSIMA Anterior, Posterior, and Combined Pelvic Floor Repair Systems consist of pre-cut GYNECARE GYNEMESH PS Mesh Implant(s), and instruments to facilitate Mesh Implant placement and postoperative support (see Figure 1). The following table summarizes the components included with each System:

PELVIC FLOOR REPAIR SYSTEM	COMPONENTS (see Figure 1)				
	Mesh Implant in Carrier (A)	Vaginal Support Device – Balloon Assembly (B&C)	Anterior Insertor (D)	Posterior Insertor (E)	Syringe (F)
Anterior	1	1	1		1
Posterior	1	1		1	1
Combined	2	1	1	1	1

Table 1 – GYNECARE PROSIMA Pelvic Floor Repair System Components

GYNECARE GYNEMESH PS

GYNECARE GYNEMESH PS is mesh constructed of knitted filaments of extruded polypropylene identical in composition to PROLENE™ Polypropylene Suture, (ETHICON, INC.). This material, when used as a suture, has been reported to be nonreactive and to retain its strength indefinitely in clinical use. The mesh affords excellent strength, durability, and surgical adaptability, with sufficient porosity for necessary tissue ingrowth. Blue PROLENE Suture monofilaments have been incorporated to produce contrast striping in the mesh. The mesh is constructed of reduced-diameter monofilament fibers, knitted into a unique design that results in a mesh that is approximately 50 percent more flexible than standard PROLENE™ Polypropylene Mesh. The mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The bi-directional elastic property allows adaptation to various stresses encountered in the body.

Mesh Implant

The Mesh Implant is constructed from GYNECARE GYNEMESH PS. The Mesh Implants are pre-cut in a Y-shape for repair of anterior, posterior and/or apical vaginal defects. See Figure 2. The Mesh Implant has 2 straps and a central body. There is an apical tab on the proximal end for tacking down with suture to minimize movement of the Mesh Implant during strap placement. There is a distal groove on the distal end to aid in alignment of the Mesh Implant. There are pre-formed pockets on the Mesh Implant straps to enable placement with the Inserters. The Mesh Implant is provided in an Implant Carrier comprised of uncoated Tyvek® and a clear plastic film, designed for easy removal of the Mesh Implant.

Anterior Insertor

The Anterior Insertor is a single-patient-use instrument designed to facilitate the insertion of the Mesh Implant straps into the previously dissected anterior tissue channels. **NOTE: The Anterior Insertor is not intended to dissect tissue.** The Anterior Insertor is designed to be compatible with the Mesh Implant pockets to enable strap placement on both sides of the patient in the anterior compartment. See Figures 3 and 4.

Posterior Insertor

The Posterior Insertor is a single-patient-use instrument designed to facilitate insertion of the Mesh Implant straps into the previously dissected posterior tissue channels. **NOTE: The Posterior Insertor is not intended to dissect tissue.** A standard needle holder/driver attaches to the Posterior Insertor as a stabilizer for controlled insertion. The Posterior Insertor is designed to be compatible with the Mesh Implant pockets to enable strap placement on both sides of the patient in the posterior compartment. See Figure 5.

Vaginal Support Device (VSD)

The VSD is a single-patient-use device designed to provide postoperative support for the vaginal tissues after placement of the mesh and closure of the vaginal incision(s). The apical end is the widest end of the VSD and contains trimmable sections. After initial sizing in the patient, the size of the VSD can be adjusted to conform to the patient's anatomy by trimming off designated apical sections. The VSD resides in the upper 2/3 of the vagina for 3 to 4 weeks and is then removed from the patient. See Figure 6.

Balloon

The Balloon is a single-patient-use device designed to replace postsurgical vaginal gauze packing. The Balloon's volume is adjustable in order to fill the vaginal canal, and for abutment of the vaginal wall to the Mesh Implant. The Balloon is provided pre-attached onto the VSD. Figure 7 shows the deflated Balloon without the VSD attached. The Balloon remains in the patient for up to 1 day.

Syringe

A 50-mL syringe is provided to inflate the Balloon.

SECTION 1: PRINCIPLES OF THE PROCEDURE USING THE GYNECARE PROSIMA SYSTEM

A pelvic floor repair procedure using the GYNECARE PROSIMA System aims to achieve an anatomical, durable, and standardized repair of pelvic organ prolapse. Depending on the site of the prolapse and surgeon's preference, the repair can be anterior and/or posterior. Hysterectomy or uterine conservation can be combined with the procedure using the GYNECARE PROSIMA System. If indicated, a perineal repair or a suburethral sling for the treatment of stress urinary incontinence can be performed concomitantly when using the GYNECARE PROSIMA System. A retropubic or transobturator suburethral sling can be used.

The prolapse repair is achieved by the placement of 1 or 2 Mesh Implants via a vaginal approach. At the completion of surgery, a VSD with an inflatable Balloon is placed in the vagina for sizing and then the VSD is sutured into place, thus supporting the vagina and the Mesh Implant(s) during tissue ingrowth. Once inflated, the Balloon replaces traditional gauze packing by filling the vaginal cavity and abutting the Mesh Implant(s) to the vagina. The day after surgery, the Balloon is deflated and removed from the vagina without dislodging the VSD. The VSD remains in place for a maximum of 4 weeks following surgery, during tissue ingrowth into the Mesh Implant(s).

SECTION 2: RATIONALE FOR THE GYNECARE PROSIMA SYSTEM

Following conventional surgery for pelvic organ prolapse, the repaired tissues are exposed to increases in intra-abdominal pressure as the patient mobilizes, coughs, vomits, and strains with bowel evacuation. These rises in intra-abdominal pressure may adversely affect the healing of the vaginal repair and may lead to surgical failure and recurrent prolapse. By reinforcing the vaginal repair with the Mesh Implant and supporting the vagina with the VSD for 3 to 4 weeks following surgery, the GYNECARE PROSIMA System is designed to reduce the risk of surgical failure and recurrent prolapse.

During the anterior vaginal repair the body of the Mesh Implant is intended to be placed without tension between the urinary bladder and the upper 2/3 of the vagina, extending laterally at the level of the arcus tendineus fascia pelvis (ATFP). During the posterior vaginal repair, the Mesh Implant body is intended to be placed without tension between the rectum and upper 2/3 of the vagina, fitting laterally over the levator ani muscles. The apical section of the Mesh Implant body is intended to reach the vaginal apex. Anteriorly, the Mesh Implant may be tacked to the pre-vesical tissue or cervix. Posteriorly, the Mesh Implant may be tacked to the pre-rectal tissue or cervix.

The VSD supports the vaginal tissues after surgery and facilitates abutment of the vaginal tissues against the Mesh Implant until tissue ingrowth occurs. Tissue ingrowth through the Mesh Implant occurs during the 3 to 4 weeks following surgery. Use of the GYNECARE PROSIMA System avoids the need for dissection outside the pelvic cavity, and avoids passage of suture and instruments through the obturator foramen and sacrospinous ligament, thus making surgery simpler to perform.

Hysterectomy

The surgeon's preference and the patient's needs determine if a concomitant hysterectomy is required. When a hysterectomy is performed, closure of the cul-de-sac peritoneum is recommended to avoid contact of the Mesh Implant with the bowel. A "T" incision closure should be avoided as this may increase the risk of mesh exposure. When vaginal hysterectomy is performed together with either or both anterior and posterior repair, the hysterectomy incision should first be closed transversely, and then the repair incisions should be made such that they do not connect with the previously closed hysterectomy incision. This is done to prevent the creation of a "T" incision.

Uterine Conservation

The GYNECARE PROSIMA System is suitable for use in situations when the surgeon or patient elects to conserve the uterus.

Vaginal Incisions

The vaginal incisions in the procedure using the GYNECARE PROSIMA System are the same as those used by the surgeon for routine vaginal repair surgery. Incisions should be made through the full depth of the vaginal wall to reduce the potential of mesh exposure.

Mesh Implant Placement

The Mesh Implants are held in place by the VSD until tissue ingrowth occurs. Therefore, it is unnecessary to fix the Mesh Implant straps into position. The apical portion of the Mesh Implant may be tacked onto the fascia in the midline at the vaginal apex using suture such as 2-0 MONOCRYL™ (Poliglecaprone 25) Suture or 2-0 Coated VICRYL™ (polyglactin 910) Suture. The vaginal epithelium should not be sutured onto the Mesh Implant.

Vaginal Preservation

Removing or excising too much vaginal epithelium should be avoided. Some tissue retraction may occur following surgery, and reduced vaginal capacity may be worsened if too much vaginal epithelium has been removed.

Three Levels of Vaginal Support

There are 3 levels of support to the vagina commonly known for vaginal repair. Use of the GYNECARE PROSIMA System in a procedure is intended to provide level I and II of this support as follows:

Level I - Suspension and Support (upper third of vagina)

The upper third of the vagina (including the vault following hysterectomy) and uterus are supported by 2 mechanisms. Firstly, direct support for the uterus and upper vagina is provided by the parametrium (cardinal and utero-sacral ligaments) and paracolpium fibers. These fibers act like suspensory ligaments and arise from the fascia of the piriformis muscle, sacrotuberous ligament, and lateral sacrum, and insert into the lateral upper third of the vagina and posterolateral aspect of the cervix. Secondly, indirect support for the uterus and upper vagina is provided by the levator plate, formed by the fusion of the right and left levator ani muscles between the rectum and coccyx. Uterine and vaginal vault prolapse occur as a consequence of failure of these direct and indirect supporting mechanisms. This is likely to involve weakness of the muscular pelvic floor and suspensory fibers of the parametrium and upper paracolpium. The aim of prolapse surgery at level I is to recreate direct and indirect supporting mechanisms. The GYNECARE PROSIMA System uses the Mesh Implant

straps to abut onto each obturator internus muscle and the overlying parietal fascia in the anterior vaginal repair, and Mesh Implant straps about the sacrospinous ligaments in the posterior vaginal repair. This provides direct support by suspension and indirect support by providing a broad area of Mesh Implant support for the upper vagina and uterus.

Level II - Lateral Attachment (mid third of vagina)

The mid-vagina is attached laterally and directly to the muscles on the pelvic sidewall by the arcus tendineus fasciae pelvis (ATFP). At this level, the anterior and posterior vaginal walls are stretched between right and left lateral attachments. At level II, prolapse repair aims to reattach the lateral mid-vagina onto the musles of the pelvic sidewall. Central defects of the mid-vagina also require support at level II. Use of the GYNECARE PROSIMA System in a procedure recreates lateral attachment of the vagina onto the pelvic sidewall muscles and also provides central fascial reinforcement after tissue ingrowth.

Level III – Fusion (lower third of vagina)

NOTE: Dissection in this area is not required when using the GYNECARE PROSIMA System.

At level III, anteriorly the lower third of the vagina fuses with the perineal membrane and urethra. Posteriorly, the lower third of the vagina fuses with the perineal body and levator ani muscles. The tissues in this area are repaired without Mesh Implant, as the Mesh Implant is not intended to be used in the lower third of the vagina. The GYNECARE PROSIMA System does not address level III support defects, though they may be addressed by concomitant procedures such as perineorraphy.

SECTION 3: INSTRUCTIONS FOR USE

NOTE: Figures provided in the beginning of this document should be referenced when reading this section.

Surgical Preparation

Surgery performed with the GYNECARE PROSIMA System may be carried out under general or regional anesthesia according to the surgeon's, anesthesiologist's, and patient's preference.

The patient should be placed in the lithotomy position with the buttocks slightly overhanging the operating table and the hips flexed. At the surgeon's discretion the bladder may be drained. A catheter is required prior to balloon inflation and may be inserted at this point in the procedure.

GYNECARE PROSIMA System Use in Procedures Post-Hysterectomy

Anterior Vaginal Repair

When reinforcement of only the anterior vaginal wall is needed, only the GYNECARE PROSIMA Anterior Pelvic Floor Repair System should be used. This contains 1 Mesh Implant and a specially designed Anterior Inserter for use in an anterior vaginal repair. After the required vaginal incisions and dissections are made, tissue channels are created in the anterior compartment for placement of the Mesh Implant straps using the Anterior Inserter. **NOTE: The Anterior Inserter is not to be used for tissue dissection.**

Anterior Vaginal Dissection

The anterior vaginal epithelium is dissected off the bladder. Dissect the full thickness of the vaginal wall. This dissection should be facilitated by subepithelial hydrodissection. Superficial dissection of the vaginal wall or separating the vaginal wall into 2 layers should be avoided. Such dissection may result in a very thin vaginal wall and may also compromise vaginal wall blood supply, increasing the risk of mesh exposure. Laterally, continue the dissection towards the pelvic sidewall and to the ischial spine.

Anterior Channel Dissection and Mesh Implant Placement

For the purpose of this description, perform the dissection to create channels for the Mesh Implant straps first on the right side of the patient, then on the left. These channels are created in order to place the Mesh Implant such that the distal section of the straps lies flush against the pelvic side wall and parietal fascia of the obturator internus muscle. To place these straps, commence dissection by palpating and identifying the ischial spine on both sides. **NOTE: This dissection may alternatively be started with scissors using a "push-spread" technique, so that the tips of the scissors always remain anterior to the ischial spine.** Follow the initial dissection by gentle finger dissection to the ischial spine. Once contact is made with the ischial spine, sweep the index finger to create a space anterior and superior to the ischial spine. See Figure 8A. The direction of this dissection is perpendicular to the pelvic sidewall and creates a space approximately 2 cm in width and 3 cm in height. The anterior dissection does not involve dissection onto the sacrospinous ligaments. This dissection creates a channel anterior and superior to the ischial spine and superficial to the ATFP, the obturator internus muscle, and its parietal fascia. Repeat the same dissection on the left side.

Plication of the pre-vesical tissue is not required. However, if plication is performed, only the central portion of this tissue is plicated. This avoids making the dissected area too narrow. Place the Mesh Implant over the pre-vesical tissue with the strap pockets facing upwards. If tacking is to be performed it should be done at this point in the procedure by placing suture such as 2-0 MONOCRYL Suture or 2-0 Coated VICRYL Suture in the apex of the vagina and threading through the apical tab of the Mesh Implant. The tack may be tied down at this time or after the straps are placed. Tacking the distal groove of the Mesh Implant is optional and may be done with suture such as 2-0 MONOCRYL Suture or 2-0 Coated VICRYL Suture.

Using the Anterior Inserter, place the Mesh Implant straps into each right and left channel created by the dissection anterior and superior to the ischial spine (as described above). **NOTE: The curved ends of the Anterior Inserter are twisted in opposite directions, and there are arrows on each end indicating direction for placement.** With the arrow pointing towards the patient's right side, insert the tip of the Anterior Inserter into the Mesh Implant strap pocket (see Figure 8B) on the patient's right side. **NOTE: Counter-traction may help to keep the pocket loaded on the Anterior Inserter.** Keep the Anterior Inserter in a vertical position, such that the curved part of the instrument is against the posterior vaginal wall. Then direct the Anterior Inserter, with strap loaded, into the previously created tissue channel (see Figure 8C) until the handle comes in contact with the labia majora on the contra-lateral side. This is accomplished by positioning the handle portion of the Anterior Inserter in an upward-vertical direction such that the leading edge and pocket goes towards the ischial spine. Once positioned, cant the handle downward to the near-horizontal position, while maintaining the handle in contact with the contra-lateral thigh. **NOTE: Retracting the bladder with a standard surgical instrument may be helpful for initial placement in the channel. If desired, use an index finger in the channel to guide the initial placement of the Anterior Inserter against the labia majora on the contra-lateral side, prior to lowering the handle.** Pushing slightly upward ensures that the strap pockets are positioned appropriately and the apical section of the Mesh Implant will abut the vaginal apex. **NOTE: If resistance is felt during strap insertion, determine the cause before proceeding. Continuing to advance the inserter while under resistance may result in damage to the Mesh Implant, or over-insertion causing damage to critical tissue structures.**

To remove the Anterior Inserter, cant the handle back to the vertical position before withdrawing, leaving the strap in the channel. **NOTE: Insert first strap completely. NOTE: If the Anterior Inserter is pulled out before the Mesh Implant strap is delivered to the target, the strap will need to be removed, re-loaded, and re-inserted.** Repeat this on the opposite side of the patient by flipping the Anterior Inserter and inserting the end, with the arrow pointing to the patient's left side, into the other pocket. Figure 8D shows both straps placed. **NOTE: During placement of the second strap, take care to avoid movement of the Mesh Implant and confirm that the Mesh Implant is NOT twisted.**

Position the body of the Mesh Implant loosely over the underlying vaginal tissue. Folding or twisting of the body and straps should be avoided. The Mesh Implant body may require trimming depending on the vaginal dimensions or amount of lateral dissection. The vaginal epithelium may be trimmed, but excessive removal of vaginal epithelium

should be avoided. Close the epithelium over the Mesh Implant without using interlocking sutures (as described below, see Figure 8E). The final placement of the Mesh Implant in the anterior compartment is shown in Figure 8F.

NOTE: Ensure hemostasis is achieved before and during closure of the vaginal incisions.

Close the vaginal incisions without interlocking or figure-of-eight sutures. This is to avoid de-vascularizing the vaginal epithelium along the incision lines and to reduce mesh enson. Preferably the epithelium is closed in 2 layers to obtain a relatively thick suture line at the site of the vaginal incision. Close the deeper layer using a continuous subepithelial non-interlocking stitch with suture such as 2-0 MONOCRYL Suture or 2-0 MONOCRYL™ Plus Antibacterial (Poliglecaprone 25) Suture. Then close the epithelium by a non-interlocking continuous everting mattress stitch, using suture such as 2-0 Coated VICRYL Suture or 2-0 Coated VICRYL™ Plus (polyglactin 910) Antibacterial Suture. **NOTE: Place Mesh Implant in the upper 2/3 of vagina, taking care to trim Mesh Implant if beyond upper 2/3.** If not done already, cystoscopy is recommended to exclude urinary tract injury.

Alternatively, a single-layered closure of the vaginal wall can be performed. A continuous everting, non-interlocking mattress stitch or interrupted stitches of suture such as 2-0 Coated VICRYL Suture or 2-0 Coated VICRYL Plus Suture may be used.

Posterior Vaginal Repair

When reinforcement of only the posterior vaginal wall is needed, only use the GYNECARE PROSIMA Posterior Pelvic Floor Repair System. This contains 1 Mesh Implant and a specially designed Posterior Inserter that is used for the posterior vaginal repair. After making the required vaginal incisions and dissections, create tissue channels in the posterior compartment in which to place the Mesh Implant straps. **NOTE: The Posterior Inserter is not to be used for tissue dissection.**

Posterior Vaginal and Channel Dissection

Dissect the posterior vaginal epithelium off the pre-rectal tissue. As with the anterior vaginal wall, the full thickness of the posterior vaginal wall should be dissected. This dissection should be facilitated by subepithelial hydro-dissection. Continue the dissection laterally on each side to the levator ani muscles at the level of the ischial spine. Then continue dissection through each of the rectal pillars and onto, but not through, each sacrospinous ligament, creating channels in which the Mesh Implant straps will be placed. See Figure 9A.

Management of preexisting enterocele is optional, but if performed, may be carried out at this stage according to the surgeon's preferred technique.

If the peritoneal cavity is opened during either anterior or posterior dissection, it must be closed prior to mesh placement.

Posterior Mesh Implant Placement

Plication of the pre-rectal tissue is not required. However, if plication of the pre-rectal tissue is performed, only the central portion of the pre-rectal tissue is plicated. This avoids making the dissected area too narrow. Place the Mesh Implant over the pre-rectal tissue with the strap pockets facing upwards. If tacking is to be performed it should be done at this point in the procedure by placing suture such as 2-0 MONOCRYL Suture or 2-0 Coated VICRYL Suture in the apex of the vagina and threading through the apical tab of the Mesh Implant. The tack may be tied down at this time or after the straps are placed. Tacking the distal groove of the Mesh Implant is optional and may be done with suture such as 2-0 MONOCRYL Suture or 2-0 Coated VICRYL Suture.

Using the Posterior Inserter, place the Mesh Implant straps into each right and left channel created by the dissection towards each sacrospinous ligament (as described above). Grasp the Posterior Inserter using a straight needle holder/driver, as shown in Figure 9B. **NOTE: Place the tip of the needle holder/driver inside the straight grooved end of the Posterior Inserter.** Ensure that the connected Posterior Inserter is in-line with the handle of the needle holder/driver. Insert the tip of the Posterior Inserter into the strap pocket on the patient's right side (see Figure 9B). Then, direct the Posterior Inserter, with strap loaded, into the previously created tissue channel (see Figure 9C), keeping the position of the handle of the needle holder/driver upright. Proceed to insert the full length of the strap into the channel so that the base of the strap meets the superior limit of the fascial dissection. **NOTE: Insert first strap completely. If the inserter is pulled out before the strap is delivered to the target, the strap will need to be removed, re-loaded, and re-inserted.** **NOTE: Take care not to insert too deeply to avoid damage to critical tissue structures. NOTE: If resistance is felt during strap insertion, determine the cause before proceeding. Continuing to advance the inserter while under resistance may result in damage to the Mesh Implant or over-insertion, causing damage to critical tissue structures.** Withdraw the Posterior Inserter along the insertion path, leaving the strap in the channel. The straps abut, but do not penetrate, the sacrospinous ligaments. Do not place sutures into the sacrospinous ligaments. Repeat the procedure on the patient's left side with the second strap. Figure 9D shows both straps placed. **NOTE: During placement of the second strap, take care to avoid movement of the Mesh Implant and confirm that the Mesh Implant is NOT twisted.**

Position the body of the Mesh Implant loosely over the underlying vaginal fascia. Avoid folding or twisting the Mesh Implant body and straps. Depending on the vaginal dimensions, or the amount of lateral dissection, the Mesh Implant body may require trimming. The posterior vaginal wall epithelium may be trimmed but excessive removal of vaginal epithelium should be avoided. Close the posterior vaginal wall epithelium over the Mesh Implant without using interlocking sutures (as described below). The final placement of the Mesh Implant in the posterior compartment is shown in Figure 9E.

NOTE: Ensure hemostasis is achieved before and during closure of the vaginal incisions.

Close the vaginal incisions without using interlocking or figure-of-eight sutures. This is to avoid de-vascularizing the vaginal epithelium along the incision lines and to reduce mesh erosion. Preferably close the epithelium in 2 layers to obtain a relatively thick suture line at the site of the vaginal incision. Close the deeper layer using a continuous subepithelial non-interlocking stitch with suture such as 2-0 MONOCRYL Suture or 2-0 MONOCRYL Plus Antibacterial Suture. Then close the epithelium with a non-interlocking continuous everting mattress stitch, using suture such as 2-0 Coated VICRYL Suture or 2-0 Coated VICRYL Plus Suture. **NOTE: Place Mesh Implant in the upper 2/3 of vagina, taking care to trim Mesh Implant if beyond upper 2/3.** At the completion of surgery, a digital rectal examination is required to exclude rectal injury.

Alternatively, a single-layered closure of the vaginal wall can be performed. A continuous everting, non-interlocking mattress stitch or interrupted stitches of suture such as 2-0 Coated VICRYL Suture or 2-0 Coated VICRYL Plus Suture may be used.

Combined Anterior and Posterior Vaginal Repair

When both anterior and posterior vaginal wall reinforcement is needed, the GYNECARE PROSIMA Combined Pelvic Floor Repair System is used. This contains 2 identical Mesh Implants, one for the anterior vaginal repair and the second for the posterior vaginal repair. Use only the curved Anterior Inserter for an anterior repair and only the straight Posterior Inserter for a posterior repair. Perform the anterior and posterior vaginal repairs as described above. It is recommended that the anterior vaginal repair be performed first. The final placement of Mesh Implants in the anterior and posterior compartments is shown in Figure 10. At the completion of surgery, cystoscopy is recommended to exclude urinary tract injury. A digital rectal examination is required to exclude rectal injury.

GYNECARE PROSIMA System Use with Uterine Preservation (Hysteropexy)

If the prolapsed uterus is conserved, the apical tab of the Mesh Implant should be fixed to the cervix. Fixation of the Mesh Implant onto the cervix should occur at the level of the pubo-cervical ring when placed during the anterior or posterior vaginal repair.

When the uterus is conserved during an anterior vaginal repair the pubo-cervical ring is exposed during the anterior vaginal dissection. Place a 2-0 PROLENE Suture firmly into the anterior aspect of the pubo-cervical ring. This suture is also placed through the apical tab of the Mesh Implant. The PROLENE Suture at the tab is tied after the Mesh Implant straps are in place. This secures the Mesh Implant to the anterior surface of the cervix at the level of the pubo-cervical ring and ensures the Mesh Implant distends with the vagina as the VSD is properly positioned.

In the posterior repair, attach the Mesh Implant to the posterior cervix at, or above, the level of the pubo-cervical ring. The cul-de-sac may be opened during the attachment of the Mesh Implant to the cervix. Close the peritoneum of the cul-de-sac above this suture to prevent bowel adhering to the Mesh Implant. If the surgeon chooses not to open the cul-de-sac, the pubo-cervical ring is exposed during the posterior vaginal dissection. A 2-0 PROLENE Suture is placed firmly into the posterior aspect of the pubo-cervical ring. This suture is also placed through the apical tab of the Mesh Implant. The PROLENE Suture is tied after the Mesh Implant straps are in place. This secures the Mesh Implant to the posterior surface of the cervix at the level of the pubo-cervical ring.

When used for both anterior and posterior vaginal repairs, the Mesh Implants should be fixed to the anterior and posterior aspects of the cervix as described above (see Figure 11).

Mesh Implant Hygiene

During surgery, irrigate the vaginal wounds with saline. Keep the handling of the Mesh Implant to a minimum and practice good mesh hygiene.

Placement of the VSD and Balloon

At the completion of surgery, place an appropriately sized VSD with attached Balloon in the vagina and suture it in position to prevent dislodgement. The VSD has 3 potential sizes (small, medium and large) and can be customized by the surgeon to suit the vaginal length of the patient as follows.

VSD Fitting and Trimming

The VSD is provided in its largest size. Determine the appropriate size of the VSD for the patient by using the VSD itself to assess fit to the patient. This is done by placing the large size VSD in the vagina between the distended apex and the hymenal ring. To insert the VSD into the vagina, grasp at the widest point of the VSD and fold along the longitudinal axis with the Balloon facing upwards (see Figure 12). The widest point of the VSD is inserted first so that the suture holes are located just above the hymenal ring. **NOTE: Do not remove or damage the Balloon during VSD sizing.** Proper size is achieved when the VSD fits snugly in the upper 2/3 of the distended vagina with the distal end and suture eyelets 1 cm above the hymenal ring (see Figure 13).

If the large size fits then the VSD is not modified. If the medium size is required, then the uppermost section is removed by carefully trimming using only the tips of curved Mayo scissors to take small bites and to ensure a smooth cut edge. Care should be taken to minimize the amount of material remaining at the cut areas. **NOTE: It is important to fit the VSD very carefully. Once a VSD is cut it cannot be made larger and the cut sections cannot be reattached.** Move the Balloon out of the way during trimming (see Figure 14). **Care should be taken to avoid damaging the Balloon during trimming of the VSD.**

If the medium size fits then no further trimming is required. If the small size is required, then the remaining section is removed as above. Move the Balloon out of the way during trimming to avoid damaging it.

Once the VSD is properly sized and the Balloon is repositioned, the assembly can be inserted into the patient's vagina. **NOTE: To minimize risk of perforation of the Balloon, do not use any instruments to assist with insertion of the VSD or of the Balloon.** If the Balloon becomes damaged, remove the Balloon from the VSD and use gauze packing to fill the vaginal cavity.

After the assembly is properly positioned in the upper 2/3 of the patient's distended vagina, secure the VSD in place by placing a single throw of suture through each VSD suture eyelet and into the posterior vaginal wall epithelium, laterally and above the hymen on each side, as shown in Figure 15, at the 4 and 8 o'clock positions. The right and left sutures are then tied in turn, holding the VSD firmly in position within the vagina. **NOTE: Take care not to puncture the Balloon when suturing the VSD into position.** 2-0 Coated VICRYL Suture or equivalent absorbable suture is recommended for this application.

Balloon Inflation

After suturing the VSD into position, attach the provided 50-mL syringe by twisting to lock it onto the Balloon's valve. **NOTE: After placing the VSD, a catheter is required to avoid urinary retention.** Following inflation with a small volume of ambient air (see Figure 16), palpate the full length of the Balloon with a finger to ensure the Balloon has deployed and is seated to the full extent of the vagina. Once deployment is confirmed, remove finger and continue to inflate the Balloon fully until only a fingertip fits snugly at the introitus between the Balloon and the vaginal wall. Stabilization of the VSD is recommended as inflation occurs. The inflated Balloon serves to abut the Mesh Implant onto the vaginal wall. The volume of air required to sufficiently inflate the Balloon will vary from patient to patient. **NOTE: The maximum Balloon inflation volume must not exceed 90 mL.** Once adequately inflated, detach the syringe from the valve by twisting. The Balloon's inflation line must extend out of the vagina to be affixed to the patient's thigh. The cap must be secured to the Balloon's valve to ensure that the Balloon will maintain the intended volume of air (see Figure 7). **NOTE: Do not over-tighten the cap.** If needed, the Balloon can be adjusted later, using a standard syringe to increase or decrease the volume of air within the Balloon. At any time the Balloon may be palpated or visually inspected to ensure it has maintained sufficient inflation. **NOTE: As the patient moves, the Balloon will settle in the vaginal cavity and may appear to either increase or decrease in pressure. This is normal.**

NOTE: Do not detach Balloon from VSD prior to use.

NOTE: Do not inflate the Balloon prior to its insertion in the vagina.

NOTE: After Balloon inflation, if the VSD suture eyelets have moved more than 1 cm above the hymenal ring or if there is excessive tension on the eyelet sutures, then decrease pressure on the Balloon, and if needed, reposition or resize the VSD.

NOTE: If any holes are noticeable in the Balloon, or if a leak is detected, or if the Balloon fails to remain expanded after inflation, then DO NOT use the Balloon. It should be removed from the VSD and disposed of by proper means. Use standard gauze packing in place of the Balloon.

NOTE: If the Balloon's connector plug detaches from the VSD, it should be pushed back in place.

NOTE: Do not secure the Balloon inflation line in the vagina.

NOTE: In order to prevent damage, never apply extreme bending, tension, or twisting forces to the inflation line.

NOTE: Do not apply gauze packing in the presence of a Balloon.

Balloon Removal from VSD

Using a standard syringe, completely deflate and remove the Balloon 1 day after surgery, leaving the VSD in place. **NOTE: Do not leave the Balloon inside the vagina for more than 1 day.**

1) Remove the cap from the Balloon's valve.

2) Attach a standard 50-mL (or larger) syringe to the Balloon's valve and fully deflate the Balloon (see Figure 17). It is important to completely deflate the Balloon before attempting to remove it from the VSD. **NOTE: A fully deflated balloon will cause the syringe plunger to retract after removal of all air.**

3) Remove the syringe.

4) The Balloon can then be separated from the VSD and removed from the patient by gentle pulling in a caudal direction on the inflation line at a location near the Balloon's connector plug, while providing gentle counter-traction on the distal end of the VSD with a finger. See Figure 18.

NOTE: Do not retract the Balloon unless it is fully deflated and no resistance is felt. If resistance is felt, determine the cause before proceeding. Continuing to advance or retract the Balloon while under resistance may result in movement of the VSD and/or tissue trauma to the vaginal cavity. To ensure complete deflation has occurred, reconnect the syringe and remove all air before continuing with removal.

VSD Removal from Patient

Remove the VSD from the patient approximately 3 to 4 weeks following surgery after sufficient healing has occurred. By this time the absorbable sutures may have dissolved or lost sufficient tensile strength to allow easy removal of the VSD without any suture resistance. **NOTE: Cutting of both sutures may be required for removal. NOTE: Do not leave the VSD inside the vagina for more than 4 weeks.** Remove any remaining VSD attachment sutures. Manually remove the VSD from vaginal canal, as shown in Figure 19.

Perioperative Care

Patients can receive prophylactic antibiotics administered according to the surgeon's usual practice. Antibiotics may be continued postoperatively depending on the preference of the surgeon. Thromboembolic prophylaxis may be used.

The surgeon should explain the purpose of the VSD, which remains in the vagina for up to four weeks following surgery, is to support the vagina against the mesh during the healing period. The patient should be advised that the VSD will be removed during a post-operative check-up, approximately 4 weeks following surgery. The patient should be advised that postoperative vaginal discharge may be experienced and that the VSD may move down slightly. If the patient feels that the VSD has moved down, she may gently push it up to a more comfortable position. However, if the VSD is causing significant discomfort, the patient should be informed to contact their doctor.

Following discharge from the hospital, the patient should be instructed to avoid strenuous activity for a period of 3 to 4 weeks. By this time the pelvic tissues will have incorporated into the Mesh Implant, and the patient can then resume activities of normal daily living. The patient should be advised to avoid sexual intercourse for at least 6 weeks following surgery. Pelvic floor exercises may be recommended any time after surgery.

PERFORMANCE

Animal studies show that implantation of GYNECARE GYNEMESH PS elicits a minimal to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

CONTRAINDICATIONS

- When GYNECARE GYNEMESH PS is used in infants, children, pregnant women, or women planning future pregnancies, the surgeon should be aware that this product will not stretch significantly as the patient grows.
- The GYNECARE PROSIMA System should not be used in the presence of pregnancy or purulent infections or cancers of the vagina, cervix, or uterus.

WARNINGS AND PRECAUTIONS

- Users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing the GYNECARE PROSIMA Systems.
- Use of the GYNECARE PROSIMA System has not been fully evaluated in patients with Stage IV pelvic organ prolapse. Therefore its use in these patients is not recommended.
- Acceptable surgical practice should be followed for the GYNECARE PROSIMA System as well as for the management of infected or contaminated wounds.
- Do not use the GYNECARE PROSIMA System if you think the surgical site may be infected or contaminated. If the Mesh Implant or VSD-Balloon Assembly is used in contaminated areas it must only be with the understanding that subsequent infection may require its removal.
- Postoperatively the patient should be advised to refrain from heavy lifting and/or exercise (e.g. cycling, jogging) for 3 to 4 weeks and to refrain from sexual intercourse for 6 weeks or until the physician determines it is suitable for the patient to return to her normal activities.
- Do not leave the VSD inside the vagina for longer than 4 weeks.
- Do not leave the Balloon inside the vagina for longer than 1 day.
- The GYNECARE PROSIMA System components are not intended to be used with devices other than those mentioned in this package insert.
- Avoid placing excessive tension on the Mesh Implant during handling.
- Use the GYNECARE PROSIMA Systems with care, and with attention to patient anatomy, to avoid damage to vessels, nerves, bladder, bowel, and vaginal wall perforation. Correct use of the GYNECARE PROSIMA System components will minimize risks.
- Inflate the Balloon only with ambient air.
- Palpation will confirm that the Balloon does not contain any air leaks after inflation. Complete loss of inflation may limit the Balloon's effectiveness.
- The Balloon wall is thin in order to achieve desired properties. Punctures, cuts, nicks, crushing, or overstretching can lead to a loss of inflation. The Balloon may be easily penetrated by needle or scalpel or ruptured by manipulation with a blunt instrument. Care must be exercised during handling to prevent such events. A damaged Balloon must not be used. Remove and pack with gauze.
- The Balloon inflation maximum is 90 mL. Do not over-inflate the Balloon. Excessive inflation of the Balloon may cause patient discomfort, tissue necrosis, disruption of vaginal wound postoperatively, or inability to void.
- Do not use GYNECARE PROSIMA Systems on patients who are on anti-coagulant therapy.

- Bleeding may occur postoperatively. Observe for any symptoms or signs before releasing the patient from the hospital.
- The patient should be instructed to contact the surgeon immediately if unusual pain, bleeding, or other problems occur.
- Although bladder injury is unlikely to occur with this technique, cystoscopy is recommended to be performed.
- Although rectal injury is unlikely to occur with this technique, a digital exam is required to be performed.
- Do not affix the GYNECARE GYNEMESH PS Mesh Implant with any staples, clips, or clamps as mechanical damage to the mesh may occur.
- The Mesh Implant should not be present in the lower 1/3 of vagina. If needed, trim the Mesh Implant to the junction of the lower and middle 1/3 of vaginal wall.
- Prophylactic antibiotics can be administered according to the surgeon's usual practice.

ADVERSE REACTIONS

- Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that result in implant contraction.
- Potential adverse reactions are those typically associated with pelvic organ prolapse repair procedures, including pain with intercourse and pelvic pain. These may be self-resolving over time.
- Punctures or lacerations or injury to vessels, nerves, bladder, urethra, or bowel may occur during dissection or mesh placement and may require surgical repair.
- Dissection for pelvic floor repair procedures has the potential to impair normal voiding for a variable length of time.

STERILITY

The GYNECARE PROSIMA Systems are sterilized by ethylene oxide. DO NOT RESTERILIZE any portion of the GYNECARE PROSIMA System. DO NOT REUSE any portion of the GYNECARE PROSIMA System. Reuse of this device (or portions of this device) may create a risk of product degradation and cross-contamination, which may lead to infection or transmission of bloodborne pathogens to patients and users. Do not use if package is opened or damaged. Discard all opened, unused GYNECARE PROSIMA System components.

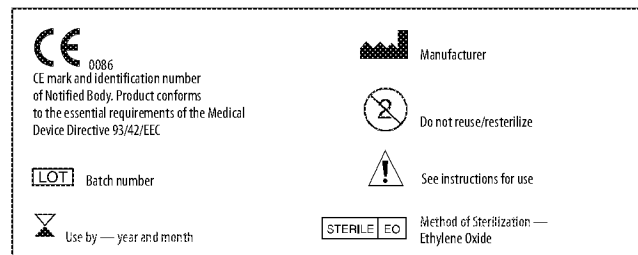
DISPOSAL

Dispose of the GYNECARE PROSIMA System components and packaging according to your facility's policies and procedures concerning biohazardous materials and waste.

STORAGE

Recommended storage conditions: controlled room temperature and relative humidity (approximately 25°C, 60% RH), away from moisture and direct heat. Do not use after expiry date.

Symbols Used on Labeling



Gynecare PROSIMA™

System til anterior støtte af bækkenbund
System til posterior støtte af bækkenbund
System til kombineret støtte af bækkenbund

DANSK

Læs venligst al information omhyggeligt.

Hvis anvisningerne ikke følges nøje, kan det resultere i, at produktet ikke fungerer korrekt og derved forårsager personskade.

FORSIGTIG: Gældende lov (i USA) begrænser salget af dette produkt til læger eller på foranledning af en læge.

Oplæring i anvendelsen af GYNECARE PROSIMA™-systemer til støtte af bækkenbunden anbefales og er tilgængelig. Kontakt firmaets produktspecialist med henblik på at arrangere en sådan oplæring.

INDIKATIONER

GYNECARE PROSIMA-systemerne, til støtte af bækkenbunden vha. anbringelsen af GYNECARE GYNEMESH™ PS ikke-resorbært PROLENE™ blødt meshimplantat, er indiceret til forstærkning af væv og langvarig stabilisering af fasciale strukturer i bækkenbunden, enten som mekanisk støtte eller brodannende materiale for den fasciale defekt. Systemerne opretholder den vaginale kanal i opheilingsperioden efter operativ behandling af prolaps af vaginalvæggen, samtidig med at de understøtter meshimplantaternes position.

BESKRIVELSE

GYNECARE PROSIMA anteriore, posteriore og kombinerede systemer til støtte af bækkenbunden består af forskåret/forskårede GYNECARE GYNEMESH PS-meshimplantat(er) og instrumenter til at lette placering af meshimplantat og postoperativ støtte (se figur 1). Tabellen herunder opsummerer de komponenter, der følger med hvert system:

SYSTEM TIL STØTTE AF BÆKKENBUND	KOMPONENTER (se figur 1)				
	Meshimplantat i emballage (A)	Vaginal støtteanordning – Ballonsamling (B og C)	Anterior indfører (D)	Posterior indfører (E)	Sprøjte (F)
Anterior	1	1	1		1
Posterior	1	1		1	1
Kombineret	2	1	1	1	1

Tabel 1 – Komponenter til GYNECARE PROSIMA-system til støtte af bækkenbund

GYNECARE GYNEMESH PS

GYNECARE GYNEMESH PS er en mesh, der består af knyttede filamenter af ekstruderet polypropylen, som svarer til den sammensætning, der er anvendt i PROLENE™-polypropylen-sutur, (ETHICON, INC.). Ved anvendelse som sutur er det rapporteret, at dette materiale er nonreaktivt, og at det bærer styrken uendeligt ved klinisk anvendelse. Meshen har fortræffelige styrke-, holdbarheds- og kirurgiske tilpasningssegner med tilstrækkelig porøsitet til nødvendig indvækst af væv. Der er indlagt blå PROLENE-suturnofilamenter for at skabe kontraststriber i meshen. Meshen er konstrueret af monofilamentfibre med reduceret diameter, som er knyttet til et unikt design, hvilket resulterer i en mesh, der er cirka 50 procent mere fleksibel end standard PROLENE™-polypropylenmesh. Meshen er knyttet vha. en proces, der sammenkæder hver enkelt fibersamling og giver elasticitet i begge retninger. Denne konstruktion gør det muligt at tilpasse meshen til enhver ønskelig form eller størrelse, uden at den trævler. Den dobbeltvirkende elastiske egenskab muliggør tilpasning til de forskellige belastninger, som kroppen udsætter den for.

Meshimplantat

Meshimplantatet er fremstillet af GYNECARE GYNEMESH PS. Meshimplantaterne er forskårede i en Y-form til støtte af anteriore, posteriore og/eller apikale vaginale defekter. Se figur 2. Meshimplantatet er udstyret med 2 stropper og en central del. Der er en apikal flig på den proksimale ende til fastsytning med sutur for at minimere bevægelse af meshimplantatet under stropplacering. Der er en distal rille i den distale ende til justering af meshimplantatet. Der er præformede lommer på meshimplantatstropperne til at muliggøre placering med indførerne. Meshimplantatet leveres i en implantatemballage, der består af uncoated Tyvek® og en gennemsigtig plastfilm, der er fremstillet, så meshimplantatet let kan tages ud.

Anterior indfører

Den anteriore indfører er et instrument til engangsbrug, der er fremstillet til at lette indføringen af meshimplantatstropperne i de tidligere dissekterede anteriore vævskanaler. **BEMÆRK: Den anteriore indfører er ikke beregnet til vævdissektion.** Den anteriore indfører er fremstillet til at være kompatibel med meshimplantatlokkerne for at muliggøre placering af stropperne på begge sider af patienten i det anteriore rum. Se figur 3 og 4.

Posterior indfører

Den posteriore indfører er et instrument til engangsbrug, der er fremstillet til at lette indføringen af meshimplantatstropperne i de tidligere dissekterede posteriore vævskanaler. **BEMÆRK: Den posteriore indfører er ikke beregnet til vævdissektion.** En standard nåleholder/-fører er fastgjort til den posteriore indfører som en stabilisator til kontrolleret indføring. Den posteriore indfører er fremstillet til at være kompatibel med meshimplantatlokkerne for at muliggøre placering af stropperne på begge sider af patienten i det posteriore rum. Se figur 5.

Vaginal støtteanordning (VSD)

VSD'en er en anordning til engangsbrug, der er designet til at yde postoperativ støtte af vaginalvævet efter placering af meshen og lukning af den eller de vaginale incisioner. Den apikale ende er den bredeste ende af VSD'en og indeholder justerbare sektioner. Efter indledende måling i patienten kan størrelsen på VSD'en justeres, så den passer til patientens anatomi, ved at afskære de viste apikale sektioner. VSD'en sidder i den øverste 2/3 af vagina i 3 til 4 uger og fjernes derefter. Se figur 6.

Ballon

Ballonen er en anordning til engangsbrug, der har til hensigt at erstatte postoperativ vaginal tamponering med gaze. Ballonens volumen kan justeres til at fylde vaginalkanalen og til at stode vaginalvæggen op mod meshimplantatet. Ballonen leveres præficeret på VSD'en. Figur 7 viser den tømte ballon uden VSD'en fastgjort. Ballonen forbliver i patienten i op til 24 timer.

14

Sprøjte

Der medfølger en 50 ml sprøjte til at puste ballonen op.

AFSNIT 1: PRINCIPPER FOR ANVENDELSE AF GYNECARE PROSIMA-SYSTEMET

Formålet med anvendelse af GYNECARE PROSIMA-systemet til støtte af bækkenbunden er at opnå en anatomisk, holdbar og standardiseret støtte af prolaps i bækkenbunden. Afhængigt af prolapsstedet og kirurgens præference kan støtten være anterior og/eller posterior. Hysterektomi eller uterusbevarende behandling kan kombineres med anvendelse af GYNECARE PROSIMA-systemet. Hvis det indiceres, kan der samtidigt udføres en perineal støtte eller en suburetral slynge til behandling af stressinkontinens ved anvendelse af GYNECARE PROSIMA-systemet. Der kan anvendes en retropubisk eller en transobturator suburetral slynge.

Prolapsstøtten opnås ved at placere 1 eller 2 meshimplantater via en vaginal adgang. Ved fuldførelsen af indgrebet placeres en VSD med en oppustelig ballon i vagina til måling, og derefter sutureres VSD'en på plads til understøttelse af vagina og meshimplantatet/ meshimplantaterne under vævsindvækst. Når ballonen er oppustet, erstatter den traditionel gazetamponade ved at udfylde vaginalkaviteten og stode meshimplantatet eller meshimplantaterne op mod vagina. Dagen efter indgrebet tømmes ballonen og fjernes fra vagina uden at frigøre VSD'en. VSD'en forbliver på plads i maksimalt 4 uger efter indgrebet under vævsindvækst i meshimplantatet/meshimplantaterne.

AFSNIT 2: RATIONALE FOR GYNECARE PROSIMA-SYSTEMET

Efter konventionel kirurgi af prolaps i bækkenbunden udsættes det ophædte væv for øget intra-abdominalt tryk, når patienten mobiliseres, hoster, kaster op og ved anstrengelse i forbindelse med tømning af tarmen. Dette øgede intra-abdominale tryk kan påvirke den vaginale støtte negativt og føre til insufficiens og tilbagevendende prolaps. GYNECARE PROSIMA-systemet er udviklet til at reducere risikoen for operationsvigt og tilbagevendende prolaps ved at forstærke den vaginale støtte med meshimplantatet og understøtte vagina med VSD'en i 3 til 4 uger efter operationen.

Ved den anteriore vaginale støtte skal meshimplantatet placeres uden spænding mellem urimblæren og den øverste 2/3 af vagina, og udstrakt lateralt på niveau med arcus tendineus fascia pelvis (ATFP). Ved den posteriore vaginale støtte skal meshimplantatet placeres uden spænding mellem rectum og den øverste 2/3 af vagina og tilpasses lateralt over levator ani musklerne. Den apikale del af meshimplantatet er beregnet til at kunne nå den vaginale apex. Anteriort kan meshimplantatet sutureres til prævesikalt væv eller cervix. Posteriort kan meshimplantatet sutureres til det prærektale væv eller cervix.

VSD'en understøtter vaginalvævet efter indgrebet og hjælper til, at vaginalvævet støder op mod meshimplantatet, indtil der forekommer vævsindvækst. Vævsindvækst igennem meshimplantatet optræder i løbet af 3 til 4 uger efter indgrebet. Ved anvendelse af GYNECARE PROSIMA-systemet undgås behovet for dissektion uden for bækkenkaviteten, samt at sutur og instrumenter passerer igennem foramen obturatorum og de sacrospinale ligamenter, hvorved operationen bliver lettere at udføre.

Hysterektomi

Kirurgens præference og patientens behov afgør, om en samtidig hysterektomi er nødvendig. Når der er udført en hysterektomi, anbefales lukning af cul-de-sac peritoneum for at undgå, at meshimplantatet kommer i kontakt med tarmen. Undgå at udføre en T"-lukning af incisionen, da dette kan forøge risikoen for blodtægning af meshen. Når der udføres vaginal hysterektomi sammen med enten anterior eller posterior støtte eller både og, skal hysterektomiincisionen først lukkes på tværs, og derefter skal støtteincisionerne foretages, så de ikke bliver forbundet med den tidligere lukkede hysterektomiincision. Dette gøres for at forhindre dannelse af en T"-incision.

Bevarelse af uterus

GYNECARE PROSIMA-systemet er velegnet til situationer, hvor kirurgen eller patienten vælger at bevare uterus.

Vaginale incisioner

De vaginale incisioner ved anvendelse af GYNECARE PROSIMA-systemet er de samme som dem, kirurgen udfører ved rutinemæssige vaginale støtteindgreb. Incisionerne skal foretages gennem vaginalvæggen fulde dybde for at reducere risikoen for blodtægning af meshen.

Placering af meshimplantat

Meshimplantaterne holdes på plads af VSD'en, indtil der sker vævsindvækst. Det er derfor unødvendigt at fiksere meshimplantatstropperne. Den apikale del af meshimplantatet kan sutureres på fascien i midterlinjen af den vaginale apex vha. sutur såsom 2-0 MONOCRYL™ (Poliglecaprone 25) eller 2-0 Coated VICRYL™ (Polyglactin 910). Det vaginale epitel må ikke sutureres til meshimplantatet.

Vaginal bevarelse

Undgå at fjerne eller eksponere for meget vaginalt epitel. Der kan forekomme nogen vævsretraktion efter operationen, og reduceret vaginal kapacitet kan forværes, hvis der er fjernet for meget vaginalt epitel.

Tre niveauer af vaginal støtte

Der er 3 støtteniveauer af vagina, der almindeligvis er kendt for at yde vaginal støtte. Anvendelse af GYNECARE PROSIMA-systemet er beregnet til at yde niveau i og II i denne støtte på følgende måde:

Niveau I – suspension og støtte (øverste tredjedel af vagina)

Den øverste tredjedel af vagina (herunder hvelvingen efter hysterektomi) og uterus er understøttet af 2 mekanismer. Parametrium (kardinale og uterosakrale ligamenter) og paracolpium fibre yder først og fremmest direkte støtte af uterus og øvre vagina. Disse fibre fungerer som suspensoriske ligamenter og starter fra fascia i piriformis musklen, sacroblæddet og det laterale sacrum og går ind i den laterale øverste tredjedel af vagina og det posterolaterale aspekt af cervix. For det andet ydes indirekte støtte af uterus og øvre vagina af levator pladen, der dannes ved fusion af de højre og venstre levator ani muskler mellem rectum og coccyx. Prolaps af uterus og vaginal hvelving sker som følge af svigt af disse direkte og indirekte støttemekanismer. Dette involverer sandsynligvis svækkelse af bækkenbundens muskulatur og de suspensoriske fibre i parametrium og øvre paracolpium. Formålet med operation af prolaps på niveau I er at genskabe direkte og indirekte støttemekanismer. GYNECARE PROSIMA-systemet bruger meshimplantatstropperne til at stode op til hver intern lukkemuskel og den overliggende parietale fascia i den

anterior vaginale støtte, og meshimplantatstøtter støder op til de sacrospinøse ligamenter i den posteriore vaginale støtte. Dette giver direkte støtte ved suspension og indirekte støtte ved at sørge for, at et bredt område leverer meshimplantatstøtte til den øvre vagina og uterus.

Niveau II – lateral vedhæftning (midterste tredjedel af vagina)

Midtvagina hæfter lateralt til musklerne på bækkenets sidevæg med arcus tendineus fasciæ pectinis (ATFP). På dette niveau er de anterior og posteriore vaginavægge udstrakt mellem de højre og venstre laterale tilhæftninger. På niveau II har prolapsstøtten til formål at gentilhefte den laterale midtvagina til musklerne på bækkenets sidevæg. Centrale defekter i midtvagina kræver også støtte på niveau II. Anvendelse af GYNECARE PROSIMA-systemet genskaber lateralt tilhæftning af vagina til bækkenets sidevægsmuskler og giver også central fascieforstærkning efter vævsindrækst.

Niveau III – fusion (nederste tredjedel af vagina)

BEMÆRK: Dissektion i dette område kræves ikke ved anvendelse af GYNECARE PROSIMA-systemet.

Anterior på niveau III forbindes den nederste tredjedel af vagina med den perineale membran og urethra. Posterior forbindes den nederste tredjedel af vagina med den perineale del og levator ani musklerne. Vævet på dette område opheles uden meshimplantat, da meshimplantatet ikke er beregnet til at blive brugt i den nederste tredjedel af vagina. GYNECARE PROSIMA-systemet behandler ikke niveau III støttedefekter, selvom de kan behandles ved ledsagende indgreb såsom perineorafi.

AFSNIT 3: BRUGSANVISNING

BEMÆRK: Ved læsning af dette afsnit skal der refereres til figurer, der vises i begyndelsen af dokumentet.

Kirurgisk forberedelse

Operationer, der udføres med GYNECARE PROSIMA-systemet, kan udføres under helbedovelse eller lokalbedovelse i overensstemmelse med kirurgens, anæsthesilægens og patientens ønsker.

Patienten skal placeres i stensnitlæje med balderne lidt ud over operationsbordet og hofterne bøjede. Blæren kan tømmes efter kirurgens skøn. Et kateter er påkrævet inden opstilling af ballonen og kan indføres på dette tidspunkt i indgrebet.

Anvendelse af GYNECARE PROSIMA-systemet efter hysterektomi

Anterior vaginal støtte

Når det kun er nødvendigt at forstærke den anterior vaginavæg, er det kun GYNECARE PROSIMA-systemet til anterior støtte af bækkenbunden, der skal anvendes. Systemet indeholder 1 meshimplantat og en special designet anterior indfører til brug ved en anterior vaginal støtte. Når de påkrævede vaginale incisioner og dissektioner er foretaget, etableres vævskanaler i det anterior rum til placering af meshimplantatstøtterne vha. den anterior indfører. **BEMÆRK: Den anterior indfører er ikke beregnet til vævsdissektion.**

Anterior vaginal dissektion

Det anterior vaginale epitel dissekeres fra blæren. Vaginavæggens fulde tykkelse dissekeres. Denne dissektion skal afhjælpes med subepitelial hydrodissektion. Superficiel dissektion af vaginavæggen eller separering af vaginavæggen i 2 lag skal undgås. En sådan dissektion kan resultere i en meget tynd vaginavæg og kan også kompromittere blodforsyningen til vaginavæggen og øge risikoen for blottægning af mesh. Følg dissektionen lateralt mod bækkenets sidevæg og til spina ischiadica.

Anterior dissektion af kanal og placering af meshimplantat

I denne beskrivelse foretages dissektionen til etablering af kanaler til meshimplantatstøtterne først på højre side af patienten og derefter på venstre. Disse kanaler etableres for at placere meshimplantatet på en sådan måde, at den distale del af støtterne flugter med bækkenets sidevæg og parietal fascia i den interne lukkemuskel. Når disse støtter skal placeres, påbegyndes dissektionen ved at palpere og identificere spina ischiadica på begge sider. **BEMÆRK: Denne dissektion kan alternativt startes med en søk, og der kan anvendes en "skubbe-sprede" teknik, så søkens spids forbliver anterior for spina ischiadica.** Den indledende dissektion efterfølges af en forsigtig fingerdissektion til spina ischiadica. Når der er opnået kontakt med spina ischiadica, bevæges pegelfingeren, så der dannes et rum anterior og superior for spina ischiadica. Se figur 8A. Denne dissektions retning er vinkelret på bækkenets sidevæg og danner et rum, der er ca. 2 cm bredt og 3 cm højt. Den anterior dissektion involverer ikke dissektion på de sacrospinøse ligamenter. Denne dissektion danner en kanal anterior og superior for spina ischiadica og superficiel for ATFP, den interne lukkemuskel og dens parietal fascia. Den samme dissektion gentages på den venstre side.

Plikation af det prævesikale væv er ikke påkrævet. Hvis der alligevel udføres plikation, plikeres kun den centrale del af dette væv. Hermed undgår man at gøre det dissekerede område for smalt. Placer meshimplantatet over det prævesikale væv med stroplommerne vendende opad. Hvis der skal sutureres, skal det gøres på dette tidspunkt i indgrebet ved at placere sutur som 2-0 MONOCRYL eller 2-0 Coated VICRYL i den vaginale apex, og sy gennem den apikale flig på meshimplantatet. Stingene kan hæftes på dette tidspunkt, eller når støtterne er placeret. Suturening af den distale rille i meshimplantatet er valgfrit og kan gøres med en sutur som 2-0 MONOCRYL eller 2-0 Coated VICRYL.

Ved hjælp af den anterior indfører placeres meshimplantatstøtterne i både højre og venstre kanal, der er etableret ved dissektionen anterior og superior for spina ischiadica (som beskrevet herover). **BEMÆRK: De buede ender på den anterior indfører er drejet i hver sin retning, og der er pile på hver ende, der angiver retning for placering.** Med pilen mod patientens højre side indføres spidsen af den anterior indfører i meshimplantatets stroplomme (se figur 8B) ved patientens højre side. **BEMÆRK: Modtræk kan hjælpe til at holde tummen på den anterior indfører.** Hold den anterior indfører lodret, så den buede del af instrumentet vender mod den posteriore vaginavæg. Før derefter den anterior indfører, med påsat tomme, ind i den tidligere etablerede vævskanal (se figur 8C). Indbål håndtaget kommer i kontakt med labia majora på den kontralaterale side. Dette udføres ved at placere håndtagssiden på den anterior indfører i en opadgående lodret retning, så forankret og tummen peger mod spina ischiadica. Når placeringen har fundet sted, vinkles håndtaget nedefter til en næsten vandret position, mens det bevares i kontakt med det kontralaterale lår. **BEMÆRK: Retraction af blæren med et kirurgisk standardinstrument kan være nyttig ved den indledende placering i kanalen. Hvis det ønskes, føres en pegelfinger ind i kanalen for at dirigere den indledende placering af den anterior indfører mod labia majora på den kontralaterale side, inden håndtaget sænkes.** Et let opadgående skub sikrer, at stroplommerne placeres korrekt, og at den apikale del af meshimplantatet vil støde op mod den vaginale apex. **BEMÆRK: Hvis der mærkes modstand under indføring af støtterne, skal årsagen findes, inden der fortsættes. Forsæt fremføring af indføeren under modstand kan resultere i beskadigelse af meshimplantatet eller kritiske vævsstrukturer.**

For at fjerne den anterior indfører vinkles håndtaget tilbage i den lodrette stilling, før indføeren trækkes tilbage, hvorved stroppen efterlades i kanalen. **BEMÆRK: Indfør første strop helt. BEMÆRK: Hvis den anterior indfører trækkes ud, før meshimplantatstøtteren er placeret korrekt, skal stroppen fjernes, påsættes og indføres igen.** Dette gentages på den modsatte side af patienten ved at vippe den anterior indfører og indføre enden i den anden lomme med pilen mod patientens venstre side. Figur 8D viser placering af begge støtter. **BEMÆRK: Sørg for at undgå at flytte meshimplantatet, og kontrollér at meshimplantatet IKKE er snoet, under placeringen af den anden strop.**

Placer hovedparten af meshimplantatet løst over det underliggende vaginavæv. Undgå at folde og sno hovedparten og støtter. Det kan være nødvendigt at tilskære meshimplantatets hovedpart afhængigt af de vaginale mål eller mængden af lateral dissektion. Det vaginale epitel kan tilskræres, men undgå at fjerne for meget vaginalt epitel. Epitelet lukkes over meshimplantatet uden at anvende tæt sammenknyttede (interlocking) suturer (som beskrevet herunder, se figur 8E). Den endelige placering af meshimplantatet i det anterior rum vises i figur 8F.

BEMÆRK: Kontrollér, at der er opnået hæmostase før og under lukning af de vaginale incisioner.

Luk de vaginale incisioner uden tæt sammenknyttede suturer eller ottetals suturer. Dette er for at undgå at devaskularisere det vaginale epitel langs incisionslinjerne og for at reducere erosion af meshen. Epitelet skal helst lukkes i 2 lag for at opnå en relativ tyk suturlinje på stedet for den vaginale incision. Luk det dybere lag vha. en fortløbende subepitelial ikke-sammenknyttende syning med sutur som 2-0 MONOCRYL eller 2-0 MONOCRYL™ Plus antibakteriel sutur (Poliglecaprone 25). Luk derefter epitelet med en ikke-sammenknyttende fortløbende udadrettet madrasnying med sutur som 2-0 Coated VICRYL eller 2-0 Coated VICRYL™ Plus (Polyglactin 910) antibakteriel sutur. **BEMÆRK: Anbring meshimplantatet i den øverste 2/3 af vagina, og tilskær det, hvis det strækker sig ud over den øverste 2/3.** Hvis det ikke allerede er gjort, anbefales cystoskopi for at udelukke beskadigelse af urinrøret.

Alternativt kan der udføres en enkeltlagslukning af vaginavæggen. Der kan anvendes en fortløbende udadrettet ikke-sammenknyttende madrasnying eller afbrudt syning med suturer som 2-0 Coated VICRYL eller 2-0 Coated VICRYL Plus.

Posterior vaginal støtte

Når det kun er nødvendigt at forstærke den posteriore vaginavæg, anvendes GYNECARE PROSIMA-systemet til posterior støtte af bækkenbunden. Systemet indeholder 1 meshimplantat og en special designet posterior indfører, der bruges til den posteriore vaginale støtte. Når de påkrævede vaginale incisioner og dissektioner er foretaget, etableres vævskanaler i det posteriore rum til placering af meshimplantatstøtterne. **BEMÆRK: Den posteriore indfører må ikke anvendes til vævsdissektion.**

Dissektion af posterior vagina og kanal

Disseker det posteriore vaginale epitel fra det prærektale væv. Ligesom med den anterior vaginavæg skal den posteriore vaginavægs fulde tykkelse dissekeres. Denne dissektion skal afhjælpes af en subepitelial hydrodissektion. Følg dissektionen lateralt på hver side af levator ani musklerne på niveau med spina ischiadica. Følg derefter dissektionen gennem hver af de rektale kanaler og over, men ikke igennem, hvert sacrospinøse ligament, hvorved der dannes kanaler, hvor meshimplantatstøtterne skal placeres. Se figur 9A.

Behandling af forud eksisterende enterocoele er valgfrit, men kan, hvis den skal foretages, udføres på dette stadie i overensstemmelse med kirurgens foretrukne teknik.

Hvis peritonealkaviteten åbnes under enten anterior eller posterior dissektion, skal den lukkes forud for meshplaceringen.

Posterior placering af meshimplantat

Plikation af det prærektale væv er ikke påkrævet. Hvis der alligevel udføres plikation af det prærektale væv, plikeres kun den centrale del af det prærektale væv. Hermed undgår man at gøre det dissekerede område for smalt. Placer meshimplantatet over det prærektale væv med stroplommerne vendende opad. Hvis der skal sutureres, skal det gøres på dette tidspunkt i indgrebet ved at placere sutur som 2-0 MONOCRYL eller 2-0 Coated VICRYL i den vaginale apex og sy gennem den apikale flig på meshimplantatet. Stingene kan hæftes på dette tidspunkt, eller når støtterne er placeret. Suturening af den distale rille i meshimplantatet er valgfrit og kan gøres med en sutur som 2-0 MONOCRYL eller 2-0 Coated VICRYL.

Ved hjælp af den posteriore indfører placeres meshimplantatstøtterne i både højre og venstre kanal, der er etableret ved dissektionen mod hvert sacrospinøse ligament (som beskrevet herover). Tag fat i den posteriore indfører vha. en lille nåleholder/-fører, som vist i figur 9B. **BEMÆRK: Anbring spidsen af nåleholderen/-føreren inden i den lige rillede ende af den posteriore indfører.** Sørg for, at den forbundne posteriore indfører er på linje med nåleholderens/-føreren's håndtag. Indfør spidsen af den posteriore indfører i stroplommen ved patientens højre side (se figur 9B). Før derefter den posteriore indfører med påsat tomme ind i den tidligere etablerede vævskanal (se figur 9C). I det nåleholderens/-føreren's håndtag holdes lodret. Følg derefter med at føre støtternes fulde længde ind i kanalen, så bunden af stroppen møder den superiore grænse på den fasciale dissektion. **BEMÆRK: Indfør første strop helt. Hvis indføeren trækkes ud, før stroppen er placeret korrekt, skal stroppen fjernes, påsættes og indføres igen. BEMÆRK: Sørg for ikke at føre stroppen for dybt ind for at undgå at beskadige kritiske vævsstrukturer. BEMÆRK: Hvis der mærkes modstand under indføring af støtterne, skal årsagen findes, inden der fortsættes. Forsæt fremføring af indføeren under modstand kan resultere i beskadigelse af meshimplantatet eller kritiske vævsstrukturer.** Træk den posteriore indfører tilbage langs insertionsbanen, så stroppen efterlades i kanalen. Stroppen støder op til, men penetrerer ikke, de sacrospinøse ligamenter. Der må ikke placeres suturer i de sacrospinøse ligamenter. Gentag indgrebet på patientens venstre side med den anden strop. Figur 9D viser placering af begge støtter. **BEMÆRK: Sørg for at undgå at flytte meshimplantatet, og kontrollér at meshimplantatet IKKE er snoet, under placeringen af den anden strop.**

Placer hovedparten af meshimplantatet løst over den underliggende vaginale fascia. Undgå at folde og sno meshimplantatets hovedpart og støtter. Det kan være nødvendigt at tilskære meshimplantatets hovedpart, afhængigt af de vaginale mål eller mængden af lateral dissektion. Det posteriore vaginale vægsepitel kan tilskræres, men undgå at fjerne for meget vaginalt epitel. Luk det posteriore vaginale vægsepitel over meshimplantatet uden at anvende tæt sammenknyttede (interlocking) suturer (som beskrevet herunder). Den endelige placering af meshimplantatet i det posteriore rum vises i figur 9E.

BEMÆRK: Kontrollér, at der er opnået hæmostase før og under lukning af de vaginale incisioner.

Luk de vaginale incisioner uden tæt sammenknyttede suturer eller ottetals suturer. Dette er for at undgå at devaskularisere det vaginale epitel langs incisionslinjerne og for at reducere erosion af meshen. Epitelet skal helst lukkes i 2 lag for at opnå en relativ tyk suturlinje på stedet for den vaginale incision. Luk det dybere lag vha. en fortløbende subepitelial ikke-sammenknyttende syning med sutur som 2-0 MONOCRYL eller 2-0 MONOCRYL Plus antibakteriel sutur. Luk derefter epitelet med en ikke-sammenknyttende fortløbende udadrettet madrasnying med sutur som 2-0 Coated VICRYL eller 2-0 Coated VICRYL Plus. **BEMÆRK: Anbring meshimplantatet i den øverste 2/3 af vagina, og tilskær det, hvis det strækker sig ud over den øverste 2/3.** Efter indgrebet skal der foretages en rektal eksplorering for at udelukke rektal læsion.

Alternativt kan der udføres en enkeltlagslukning af vaginavæggen. Der kan anvendes en vedvarende, udadrettet ikke-sammenknyttende madrasnying eller afbrudt syning med suturer som 2-0 Coated VICRYL eller 2-0 Coated VICRYL Plus.

Kombineret anterior og posterior vaginal støtte

Når det er nødvendigt både at forstærke den anterior og posteriore vaginavæg, anvendes GYNECARE PROSIMA-systemet til kombineret støtte af bækkenbunden. Systemet indeholder 2 identiske meshimplantater, et til den anterior vaginale støtte og det andet til den posteriore vaginale støtte. Brug kun den buede anterior indfører til den anterior støtte og kun den lige posterior indfører til den posterior støtte. Udfor de anterior og posteriore vaginale støtter som beskrevet herover. Det anbefales at udføre den anterior vaginale støtte først. Den endelige placering af meshimplantaterne i de anterior og posteriore rum vises i figur

10. Efter indgrebet anbefales cystoskopi for at udelukke beskadigelse af urinrøret. Det er nødvendigt at udføre en digital rektal undersøgelse for at udelukke rektal lækage.

Anvendelse af GYNECARE PROSIMA-systemet med bevarelse af uterus (hysteropeksi)

Hvis den fremfaldne uterus bevares, skal den apikale flig på meshimplantatet fikseres til cervix. Fiksering af meshimplantatet til cervix skal ske på niveau med den pubo-cervikale ring ved placering under den anteriore eller posteriore vaginale støtte.

Når uterus bevares under en anterior vaginal støtte, fritlægges den pubo-cervikale ring under den anteriore vaginale dissektion. Placer en 2-0 PDS suture forsvarligt i det anteriore aspekt af den pubo-cervikale ring. Denne sutur placeres også gennem den apikale flig på meshimplantatet. PDS-suturen ved fligen hæftes, når meshimplantatstroppen er på plads. Dette sikrer meshimplantatet til den anteriore overflade på cervix på niveau med den pubo-cervikale ring og sikrer, at meshimplantatet udspringes med vagina, når VSD'en er korrekt placeret.

I den posteriore støtte skal meshimplantatet fikseres til den posteriore cervix ved eller over niveauet for den pubo-cervikale ring. Cul-de-sac kan åbnes under meshimplantatets vedhæftning til cervix. Luk Cul-de-sac peritoneum over denne sutur for at hindre, at tarmen adhærer til meshimplantatet. Hvis kirurgen vælger ikke at åbne cul-de-sac, fritlægges den pubo-cervikale ring under den posteriore vaginale dissektion. En 2-0 PDS suture placeres forsvarligt i det posteriore aspekt af den pubo-cervikale ring. Denne sutur placeres også gennem den apikale flig på meshimplantatet. PDS-suturen hæftes, når meshimplantatstroppen er på plads. Dette sikrer meshimplantatet til den posteriore overflade på cervix på niveau med den pubo-cervikale ring.

Når meshimplantaterne anvendes til både anterior og posterior vaginal støtte, skal de fikseres til de anteriore og posteriore aspekter på cervix, som beskrevet herover (se figur 11).

Hygiejne i forbindelse med meshimplantat

Under indgrebet skylles de vaginale sår med saltvand. Håndtering af meshimplantatet skal holdes på et minimum, og der skal praktiseres god meshhygiejne.

Placering af VSD og ballon

Efter indgrebet placeres en VSD i passende størrelse med vedhæftet ballon i vagina, og den sutureres på plads for at hindre løsrivelse. VSD'en leveres i 3 størrelser (lille, medium og stor) og kan tilpasses af kirurgen, så den passer til patientens vaginal længde på følgende måde.

Tilpasning og tilskæring af VSD

VSD'en leveres i den største størrelse. Bestem den største VSD, der passer til patienten, ved at bruge selve VSD'en. Dette gøres ved at placere den store størrelse VSD i vagina mellem den udspilede apex og hymenringen. Indsæt VSD'en i vagina ved at lægge fat om det bredeste punkt på VSD'en og folde langs den langsiddende aksel med ballonen vendt opad (se figur 12). Det bredeste punkt på VSD'en indsættes først, så suturehullerne er placeret lige over hymenringen. **BEMÆRK: Ballonen må ikke fjernes eller beskadiges under VSD-måling.** Den korrekte størrelse er opnået, når VSD'en slutter tæt i den øverste 2/3 af den udspilede vagina med den distale ende og suturehullerne 1 cm over hymenringen (se figur 13).

Hvis den store størrelse passer, ændres VSD'en ikke. Hvis medium størrelsen passer, fjernes den øverste del ved forsigtigt at klippe små stykker af og sikre en jævn klippelkant udelukkende vha. spidsen på den buede Mayo saks. Sørg for at mindske mængden af materiale, der er tilbage på de afklippede områder. **BEMÆRK: Det er vigtigt at tilpasse VSD'en meget omhyggeligt. Når en VSD er klippet til, kan den ikke gøres større, og de afklippede dele kan ikke sættes på igen.** Flyt ballonen under tilklipningen (se figur 14). **Der skal udvises forsigtighed for at undgå at beskadige ballonen under tilklipning af VSD'en.**

Hvis medium størrelsen passer, kræves ingen yderligere klipping. Hvis den lille størrelse passer, fjernes den resterende del som ovenfor. Flyt ballonen under tilklipningen, så den ikke beskadiges.

Når VSD'en er målt korrekt, og ballonen er placeret igen, kan samlingen indsættes i patientens vagina.

BEMÆRK: For at mindske risikoen for perforering af ballonen må den ikke anvendes instrumentelt til hjælp ved indføringen af VSD'en eller ballonen. Hvis ballonen bliver beskadiget, fjernes den fra VSD'en, og vaginalkaviteten fyldes med gaze-forbinding.

Når samlingen er placeret korrekt i den øverste 2/3 af patientens udspilede vagina, sættes VSD'en på plads ved at anbringe et enkelt stykke sutur gennem hvert VSD-suturehul og ind i den posteriore vaginalhægs epitel lateralt og over hymen på hver side, som vist i figur 15, ved kl. 4 og kl. 8 positionerne. De højre og venstre suturer bindes derefter skiftevis, så VSD'en holdes forsvarligt på plads i vagina. **BEMÆRK: Pas på, ikke at punktere ballonen, når VSD'en sutureres på plads.** En sutur som f.eks. 2-0 Coated VICRYL eller en tilsvarende resorberbar sutur anbefales til denne anvendelse.

Oppustning af ballon

Når VSD'en er sutureret på plads, placeres den medfølgende 50 ml sprøjte på ballonventilen og drejes på plads. **BEMÆRK: Når VSD'en er placeret, er det nødvendigt at indsætte et kateter for at undgå urinretention.** Efter oppustning med en lille mængde atmosfærisk luft (se figur 16) palperes ballonens fulde længde med en finger for at sikre, at ballonen er anbragt i vaginas fulde udstrækning. Når placeringen er bekræftet, fjernes fingeren, og ballonen oppustes yderligere, indtil der kun kan placeres en fingerspids i indgangen til skeden mellem ballonen og vaginalvæggen. Det anbefales at stabilisere VSD'en efterhånden, som ballonen oppustes. Den oppustede ballon støder meshimplantatet op mod vaginalvæggen. Den luftmængde, der kræves til at puste ballonen tilstrækkeligt op, vil variere fra patient til patient. **BEMÆRK: Den maksimale volumen for en oppustet ballon må ikke overskride 90 ml.** Når ballonen er pustet tilstrækkeligt op, drejes sprøjten på ventilen. Ballonens oppustningslange skal stikke ud af vagina for at blive fastgjort til patientens lår. Hæften skal sættes på ballonventilen for at sikre, at ballonen vil bevare den påtænkte luftmængde (se figur 7). **BEMÆRK: Stram ikke hæften for hårdt til.** Hvis det er nødvendigt, kan ballonen justeres senere vha. en standardsprøjte, så luftmængden i ballonen øges eller mindskes. Ballonen kan når som helst palperes eller efteres for at sikre, at den har bevaret tilstrækkelig luft. **BEMÆRK: Efterhånden som patienten bevæger sig, flyttes ballonen på plads i vaginalkaviteten, og det kan virke, som om presset enten stiger eller aftager. Dette er normalt.**

BEMÆRK: Ballonen må ikke tages af VSD'en inden brug.

BEMÆRK: Ballonen må ikke pustes op, inden den indføres i vagina.

BEMÆRK: Hvis VSD-suturehullerne efter ballonoppustning har flyttet sig mere end 1 cm over hymenringen, eller hvis der er for stor spænding på suturehullerne, skal trykket i ballonen mindskes, og hvis det er nødvendigt, skal VSD'en flyttes eller opnåes igen.

BEMÆRK: Hvis der bemærkes huller i ballonen, eller hvis der opdages en utæthed, eller hvis ballonen ikke holder luften efter oppustning, må den IKKE anvendes. Den skal fjernes fra VSD'en og bortskaffes på behørig vis. Anvend standard gaze-forbinding i stedet for ballonen.

BEMÆRK: Hvis ballonens forbindelsesstykke løsner sig fra VSD'en, skal det skubbes tilbage på plads.

BEMÆRK: Ballonens oppustningslange må ikke fastgøres i vagina.

BEMÆRK: For at undgå at beskadige oppustningslangen må den aldrig udsættes for ekstrem bøjning, spænding eller drøjning.

BEMÆRK: Indsæt ikke gaze-forbinding ved tilstedeværelse af en ballon.

Frakobling af ballon fra VSD

24 timer efter indgrebet tømmes ballonen vha. en standardsprøjte og fjernes, mens VSD'en efterlades på plads. **BEMÆRK: Lad ikke ballonen være i vagina i mere end 24 timer.**

1) Tag hæften af ballonens ventil.

2) Fastgør en 50 ml (eller større) standardsprøjte til ballonens ventil og tøm ballonen helt (se figur 17). Det er vigtigt at tømme ballonen helt, før der gøres forsøg på at fjerne den fra VSD'en. **BEMÆRK: En helt tømt ballon vil resultere i, at sprøjtestemplet trækker sig tilbage, når al luften er fjernet.**

3) Fjern sprøjten.

4) Ballonen kan derefter separeres fra VSD'en ved forsigtigt at trække oppustningslangen i kaudal retning et sted nær ballonens forbindelsesstykke, mens der forsigtigt ydes modtryk med en finger i den distale ende af VSD'en. Se figur 18.

BEMÆRK: Træk ikke ballonen tilbage, medmindre den er helt tømt, og der ikke mærkes modstand. Hvis der mærkes modstand, findes årsagen, inden der fortsættes. Forsat fremføring eller tilbagetrækning af ballonen under modstand kan resultere i, at VSD'en flytter sig og/eller vævstraumer i vaginalkaviteten. For at sikre at ballonen er fuldstændigt tømt, fastgøres sprøjten igen, og al luft fjernes, inden udtagningen fortsættes.

Udtagning af VSD fra patient

Fjern VSD'en fra patienten ca. 3 til 4 uger efter indgrebet, når der er sket tilstrækkelig ophealing. På dette tidspunkt er de resorberbare suturer gået i opløsning eller har mistet så meget trækstyrke, at det er let at fjerne VSD'en uden suturemodstand. **BEMÆRK: Det kan være nødvendigt at klippe begge suturer over for at fjerne VSD'en.** **BEMÆRK: Lad ikke VSD'en være i vagina i mere end 4 uger.** Fjern eventuelle resterende VSD tilhæftningssuturer. Udtag VSD'en manuelt fra vaginalkanalen, som vist i figur 19.

Perioperativ pleje

Patienter kan få profylaktisk antibiotika i henhold til kirurgens normale praksis. Dette kan fortsættes postoperativt afhængigt af kirurgens skøn. Der kan anvendes tromboembolisk profylakse.

Kirurgen bør forklare, at formålet med VSD'en, som bliver siddende i vagina i op til fire uger efter operationen, er at understøtte vagina imod meshen under helingsperioden. Patienter bør informeres om, at VSD'en vil blive fjernet under en postoperativ opfølgningskonsultation, ca. 4 uger efter operationen. Patienter skal desuden informeres om, at der kan forekomme postoperativ udlad fra vagina, og at VSD'en kan flytte sig en smule nedefter. Hvis patienten føler, at VSD'en har flyttet sig nedad, kan hun forsigtigt skubbe den op til en mere behagelig position. Patienter bør imidlertid tilrådes at kontakte lægen, hvis VSD'en giver betydeligt ubehag.

Efter udskrivning fra hospitalet skal patienten undgå anstrengende aktiviteter i en periode på 3 til 4 uger. På dette tidspunkt er bækkenvævet vokset ind i meshimplantatet, og patienten kan herefter genoptage normale dagligdags aktiviteter. Patienter skal rådes til at undgå samleje i mindst 6 uger efter operationen. Bækkenbundsøvelser kan anbefales når som helst efter operationen.

YDEEVNE

Dyreforsøg viser, at implantation af GYNECARE GYNEMESH PS fremkalder en minimal til let inflammatorisk reaktion, som er kortvarig og efterfølges af dannelsen af et tyndt fibrøst vævslag, som kan vokse gennem meshens mellemrum og således inkorporere meshen i det tilstødende væv. Meshen forbliver blød og smidig, og den normale sårhelings nedsettelse ikke mærkbart. Materialet resorberes ikke, og det nedbrydes eller svækkes heller ikke af vævsenzymmer.

KONTRAINDIKATIONER

- Når GYNECARE GYNEMESH PS anvendes hos spædbørn, børn, gravide eller kvinder, der planlægger fremtidig graviditet, skal kirurgen være opmærksom på, at produktet ikke vil udvide sig signifikant, når patienten vokser.
- GYNECARE PROSIMA-systemet bør ikke anvendes ved graviditet eller purulente infektioner eller cancer i vagina, cervix eller uterus.

ADVARSLER OG FORSIGTIGHEDSREGLER

- For anvendelse af GYNECARE PROSIMA-systemer skal brugeren være fortrolig med de operationsprocedurer og -teknikker, der omfatter støtte af bækkenbunden og ikke-resorberbare mesh.
- Anvendelse af GYNECARE PROSIMA-systemet er ikke fuldt ud evalueret hos patienter med stadie IV vaginalprolaps. Anvendelse af systemet kan derfor ikke anbefales til disse patienter.
- Godkendt kirurgisk praksis skal overholdes i forbindelse med GYNECARE PROSIMA-systemet lige som ved behandling af inficerede eller kontaminerende sår.
- GYNECARE PROSIMA-systemet må ikke anvendes, hvis der er mistanke om, at incisionsstedet er inficeret eller kontamineret. Anvendelse af meshimplantatet eller VSD-ballonsamlingen i kontaminerende områder skal foregå under hensyntagen til, at efterfølgende infektion kan gøre det nødvendigt at fjerne dem.
- Efter operationen skal patienten informeres om, at løft af tunge ting og/eller motion (f.eks. cykling, jogging) skal undgås i 3 til 4 uger, og at samleje skal undgås i 6 uger, eller indtil lægen vurderer, at patienten kan vende tilbage til sine normale aktiviteter.
- Lad ikke VSD'en være i vagina længere end 4 uger.
- Lad ikke ballonen være i vagina længere end 24 timer.
- Komponenterne i GYNECARE PROSIMA-systemet er ikke beregnet til at blive brugt sammen med andre anordninger end dem, der er nævnt på pakningens indlægsseddel.
- Undgå at stramme meshimplantatet for meget under håndteringen.
- Anvend GYNECARE PROSIMA-systemerne med omhu, og vær særlig opmærksom på patientens anatomi for at undgå beskadigelse af kar, nerver, blære og tarm samt perforering af vaginalvæggen. Korrekt brug af komponenterne i GYNECARE PROSIMA-systemet vil mindske risici.
- Oppust kun ballonen med atmosfærisk luft.
- Palpering vil bekræfte, at ballonen ikke indeholder eventuelle luftutætheder efter oppustning. Fuldt lufttab kan begrænse ballonens effektivitet.

- Ballonvæggen er tynd for at opnå de ønskede egenskaber. Punkteringer, snit, hakker, sammentrykning eller overbelastning kan føre til lufttab. Ballonen kan let penetreres af en kanyler eller en skalpel eller sprænge ved manipulation med et stump instrument. Der skal udvises forsigtighed under håndtering for at forhindre sådanne hændelser. En beskadiget ballon må ikke bruges. Fjern den og indsæt gazeforbinding.
- Ballonens maksimale oppustningsvolumen er 90 ml. Ballonen må ikke pustes for hårdt op. For voldsom oppustning af ballonen kan forårsage utilpashed hos patienten, vævsnekrose, postoperative brud på vaginale sår eller manglende evne til at lade vandet.
- GYNECARE PROSIMA-systemerne må ikke benyttes til patienter, som er i antikoagulationsbehandling.
- Blødning kan opstå postoperativt. Hold øje med eventuelle symptomer eller tegn, før patienten udskrives fra hospitalet.
- Patienten skal instrueres i at kontakte kirurgen straks, hvis der opstår usædvanlige smerter, blødning eller andre problemer.
- Selvom det er usandsynligt, at der vil forekomme beskadigelse af blæren med denne teknik, anbefales det at udføre cystoskopi.
- Selvom det er usandsynligt, at der vil forekomme rektale læsioner med denne teknik, er det nødvendigt at foretage en rektal eksploration.
- GYNECARE GYNEMESH PS-meshimplantatet må ikke fastgøres med staplere, clips eller klemmer, da der kan opstå mekanisk skade på meshen.
- Meshimplantatet må ikke være i den nederste tredjedel af vagina. Hvis det er nødvendigt, afkippes meshimplantatet ved overgangen mellem den nederste og midterste tredjedel af vaginalvæggen.
- Profylaktisk antibiotika kan administreres i henhold til kirurgens sædvanlige praksis.

BIVIRKNINGER

- Potentielle bivirkninger er de, der typisk forbindes med operative implanterbare materialer, herunder potentielle infektioner, inflammation, adhæsions- og fisteldannelse, erosion, udstødelse og ardannelse, som medfører, at implantatet trækker sig sammen.
- Potentielle bivirkninger er dem, der typisk forbindes med operation af vaginalprolaps, herunder smerter i forbindelse med samleje og bækkenmerter. Disse kan forsvinde med tiden.
- Punkteringer, lacerationer eller beskadigelse af kar, nerver, blære, urethra eller tarm kan opstå under disektion eller placering af mesh og kan kræve operation.
- Disektion i forbindelse med støtteoperation af bækkenbunden indebærer risiko for at hæmme normal vandladning i et varierende tidsrum.

STERILITET

GYNECARE PROSIMA-systemerne er steriliserede mod ethylenoxid. INGEN dele i GYNECARE PROSIMA-systemet må RESTERILISERES. INGEN dele i GYNECARE PROSIMA-systemet må GENANVENDES. Genbrug af denne anordning (eller dele af denne anordning) kan skabe risiko for nedbrydning af produktet og krydskontaminering, hvilket kan lede til infektion eller overførsel af blodoverførte patogener til patienter og brugere. Må ikke anvendes, hvis emballagen er åbnet eller beskadiget. Bortskaf alle åbnede, ubrugte komponenter til GYNECARE PROSIMA-systemet.








BORTSKAFFELSE

Bortskaf komponenterne til GYNECARE PROSIMA-systemet og indpakningen i henhold til institutionens politik og procedurer vedrørende biologisk farlige materialer og affald.

OPBEVARING

Anbefalet opbevaring: ved kontrolleret stuetemperatur og relativ fugtighed (ca. 25 °C, 60 % RH), beskyttet mod fugt og direkte varme. Må ikke anvendes, hvis udløbsdatoen er overskredet.

Symboler anvendt på mærkater

	0086 CE-mærke og identifikationsnummer for bemyndiget instans. Produktet opfylder de væsentlige krav i EU-direktiv om medicinske anordninger 93/42/EØF.		Producent
	Batchnummer		Må ikke genbruges/resteriliseres
	Anvendes inden --- år og måned		Se brugsanvisningen
			Steriliseringsmetode — ethylenoxid

Gynecare PROSIMA™

Bekkenbodemreparatiesysteem anterieur
Bekkenbodemreparatiesysteem posterieur
Bekkenbodemreparatiesysteem gecombineerd

NEDERLANDS

Lees alle informatie zorgvuldig.

Het negeren van deze instructies kan een ondoelmatige werking van de hulpmiddelen tot gevolg hebben en letsel veroorzaken.

LET OP: De federale wetgeving (van de Verenigde Staten) eist dat dit apparaat uitsluitend aan of in opdracht van een arts wordt verkocht.

Gebruikers wordt geadviseerd zich te oefenen in het gebruik van het GYNECARE PROSIMA™-bekkenbodemreparatiesysteem. Hiertoe zijn trainingsmogelijkheden beschikbaar. Neem voor het maken van afspraken voor zulke trainingen contact op met de vertegenwoordiger van uw leverancier.

INDICATIES

De GYNECARE PROSIMA systemen voor bekkenbodemreparatie door plaatsing van GYNECARE GYNEMESH™ PS niet-resorbabele implantaten van PROLENE™ Soft Mesh zijn geïndiceerd voor weefselversterking en duurzame stabilisering van bindweefselsstructuren van de bekkenbodem, als mechanische ondersteuning of als overbruggingsmateriaal voor het bindweefseldefect. De systemen bieden ondersteuning aan het vaginakanaal tijdens de genezingsperiode na chirurgische behandeling van een prolaps van de vaginawand en ondersteunen tegelijkertijd de positie van de meshimplantaten.

BESCHRIJVING

De GYNECARE PROSIMA reparatiesystemen voor de anterieure, posterieure en gehele bekkenbodem bestaan uit voorgevormde GYNECARE GYNEMESH PS meshimplantaten en instrumenten voor het plaatsen van het meshimplantaat en voor post-operatieve ondersteuning (zie afbeelding 1). De onderstaande tabel biedt een overzicht van de onderdelen die van elk systeempakket deel uitmaken:

BEKKEN- BODEM- REPARATIE- SISTEEM	ONDERDELEN (zie afbeelding 1)				
	Meshimplantaat in implantaathouder (A)	VSD/ballonset (B en C)	Inbrenginstrument anterieur (D)	Inbrenginstrument posterieur (E)	Spuut (F)
Anterieur	1	1	1		1
Posterieur	1	1		1	1
Gecombineerd	2	1	1	1	1

Tabel 1 – Onderdelen van het GYNECARE PROSIMA bekkenbodemreparatiesysteem

GYNECARE GYNEMESH PS

GYNECARE GYNEMESH PS is meshmateriaal vervaardigd van tricotvezels van geëxtrudeerd polypropyleen, qua samenstelling identiek aan PROLENE™ polypropyleen hecht draad (ETHICON, INC.). Vastgesteld is dat dit materiaal bij gebruik als hecht draad niet reactief is en dat het bij klinisch gebruik zijn sterkte voor onbeperkte tijd behoudt. De mesh biedt een uitstekende sterkte, duurzaamheid en aanpasbaarheid voor chirurgische doeleinden en is voldoende poreus voor de noodzakelijke weefselingroei. Er is blauw PROLENE monofilament hecht draad materiaal in het weefsel verwerkt, waardoor een contraststreep in de mesh ontstaat. De mesh is gemaakt volgens een uniek ontwerp van samengebreide monofilamentvezels met gereduceerde diameter, wat resulteert in een mesh die ongeveer 50 procent flexibeler is dan de standaard PROLENE™ polypropyleen mesh. De mesh wordt gebreed met gebruikmaking van een proces waardoor alle knooppunten van de vezels onderling met elkaar worden verbonden en waardoor in beide richtingen elasticiteit wordt verschaft. Door deze constructie kan de mesh in iedere gewenste vorm en grootte worden geknipt zonder te rafelen. Door de elasticiteit in twee richtingen kan de mesh worden aangepast aan uiteenlopende spanningsbelastingen die in het lichaam voorkomen.

Meshimplantaat

Het meshimplantaat is vervaardigd van GYNECARE GYNEMESH PS. De meshimplantaten zijn vooraf in Y-vorm gesneden, passend voor reparatie van anterieure, posterieure en/of apicale vaginadefecten. Zie afbeelding 2. Het meshimplantaat heeft 2 bandjes en een centraal gelegen hoofdgedeelte. Op het proximale, apicale uiteinde bevindt zich een lipje dat met hecht draad kan worden vastgehecht, zodat het meshimplantaat tijdens het plaatsen van de bandjes vrijwel bewegingsloos blijft. Op het distale uiteinde bevindt zich een groef die fungeert als hulpmiddel voor het oriënteren van het meshimplantaat. Op de bandjes van het meshimplantaat zijn voorgevormde zakjes aangebracht, die plaatsing van het implantaat met de inbrenginstrumenten mogelijk maken. Het meshimplantaat wordt geleverd in een implantaathouder van ongecoat Tyvek™ en een transparante plastic folie waardoor het meshimplantaat gemakkelijk uit de houder kan worden verwijderd.

Inbrenginstrument anterieur

Het inbrenginstrument voor de anterieure bekkenbodem is een instrument voor eenmalig gebruik, waarmee het inbrengen van de bandjes van het meshimplantaat in de losgeprepareerde posterieure weefselkanalen wordt vergemakkelijkt.

OPMERKING: Het inbrenginstrument anterieur is niet bedoeld om weefsel te los te prepareren. Het inbrenginstrument voor de anterieure bekkenbodem is compatibel met de zakjes van het meshimplantaat, zodat het kan worden gebruikt voor het plaatsen van de bandjes in de anterieure bekkenholte aan beide lichaamszijden van de patiënt. Zie afbeeldingen 3 en 4.

Inbrenginstrument posterieur

Het inbrenginstrument voor de posterieure bekkenbodem is een instrument voor eenmalig gebruik, waarmee het inbrengen van de bandjes van het meshimplantaat in de losgeprepareerde posterieure weefselkanalen wordt vergemakkelijkt. **OPMERKING:** Het inbrenginstrument posterieur is niet bedoeld om weefsel te los te prepareren. Aan het inbrenginstrument voor de posterieure bekkenbodem is als stabilisator een standaard naaldhouder/naaldvoeder bevestigd, zodat het implantaat beheerst kan worden ingebracht. Het inbrenginstrument voor de posterieure bekkenbodem is compatibel met de zakjes van het meshimplantaat, zodat het kan worden gebruikt voor het plaatsen van de bandjes in de posterieure bekkenholte aan beide lichaamszijden van de patiënt. Zie afbeelding 5.

VSD (Vaginal Support Device, vaginasteun)

De VSD (Vaginal Support Device, vaginasteun) is een hulpmiddel voor eenmalig gebruik, dat de vaginaweefsels postoperatief ondersteunt, na plaatsing van het meshimplantaat en sluiting van de vaginale incisie(s). Het apicale uiteinde is het breedste deel van de VSD en gedeelten ervan zijn afknipbaar. Na aanvankelijke passing in de anatomie van de patiënt kunnen de afmetingen van de VSD aan de anatomie van de patiënt worden aangepast door het afknippen van daartoe bestemde delen van het apicale uiteinde. De VSD wordt voor een periode van 3 tot 4 weken in het bovenste tweede deel van de vagina geplaatst en wordt daarna verwijderd. Zie afbeelding 6.

Ballon

De ballon is een hulpmiddel voor eenmalig gebruik dat wordt gebruikt in plaats van een postchirurgisch gazen kompres in de vagina. Het volume van de ballon kan zodanig worden bijgesteld dat het vaginakanaal sluitend wordt gevuld en het meshimplantaat tegen de vaginawand wordt gedrukt. De ballon is bij nieuwlevering aan de VSD bevestigd. Afbeelding 7 toont de ledige ballon, zonder de daaraan bevestigde VSD. De ballon blijft maximaal een dag lang in het lichaam van de patiënt geplaatst.

Spuut

Voor het vullen van de ballon wordt een 50 ml spuit bijgeleverd.

DEEL 1: WERKINGSBEGINSELEN VAN DE PROCEDURE MET HET GYNECARE PROSIMA SYSTEEM

Met de procedure met het GYNECARE PROSIMA systeem wordt beoogd een anatomische, duurzame en gestandaardiseerde reparatie van prolaps van de bekkenorganen te realiseren. Afhankelijk van de geprobeerde anatomische locatie en de voorkeur van de chirurg kan de reparatie anterieur en/of posterieur worden uitgevoerd. De procedure met het GYNECARE PROSIMA systeem kan in combinatie met hysterectomie of conservatieve uteruschirurgie worden uitgevoerd. Wanneer dat is geïndiceerd, kan tegelijk met de procedure met het GYNECARE PROSIMA systeem penieumreparatie worden verricht of een suburetraal suspensiebandje voor behandeling van urineaire stressincontinentie worden aangelegd. Er kan gebruik worden gemaakt van een retropubische of suburetrale transobturatore tape (TOT).

De prolapsreparatie wordt gerealiseerd door plaatsing van 1 of 2 meshimplantaten via de vagina. Bij voltooiing van de operatie wordt een VSD met een vulbare ballon voor passing in de vagina geplaatst en wordt vervolgens de VSD op de juiste plaats vastgehecht, zodat de vagina en het meshimplantaat (of de meshimplantaten) tijdens de weefselingroei worden ondersteund. Nadat hij is gevuld neemt de ballon de plaats in van het traditionele gazen kompres door de vaginahalte sluitend te vullen en het meshimplantaat (de meshimplantaten) tegen de vaginawand te drukken. De dag postoperatief wordt de ballon geleegd en uit de vagina verwijderd zonder dat de VSD daarbij losraakt. De VSD blijft tot maximaal 4 weken na de operatie in situ, en in die tijd vindt weefselingroei in het meshimplantaat (de meshimplantaten) plaats.

DEEL 2: BASISPRINCIPE VAN HET GYNECARE PROSIMA SYSTEEM

Na behandeling van bekkenorgaanprolaps middels conventionele chirurgie worden de gerepareerde weefsels blootgesteld aan verhoogde intra-abdominale druk wanneer de patiënt zich mobiliseert en bij hoesten, braken en darmontlastingsdruk. Deze toename van de intra-abdominale druk kan een nadelige invloed hebben op de genezing van de vaginareparatie en kan chirurgisch falen en recidive van de prolaps tot gevolg hebben. Door versterking van de vaginareparatie met het meshimplantaat en ondersteuning van de vagina met de VSD gedurende 3 tot 4 weken postoperatief vormt het GYNECARE PROSIMA systeem een hulpmiddel voor vermindering van het risico van chirurgisch falen en recidive van de prolaps.

Tijdens anterieure vaginareparatie moet het hoofdgedeelte van het meshimplantaat spanningsvrij tussen de urineblaas en het bovenste tweede deel van de vagina worden geplaatst, lateraal uitstekend ter hoogte van de arcus tendineus fasciae pelvis (ATFP). Tijdens posterieure vaginareparatie moet het hoofdgedeelte van het meshimplantaat spanningsvrij tussen het rectum en het bovenste tweede deel van de vagina worden geplaatst, lateraal passend boven de mm. levator ani. Het apicale deel van het hoofdgedeelte van het meshimplantaat moet de apex vaginae bereiken. Aan anterieure zijde kan het meshimplantaat aan het prevesicale weefsel of aan de cervix worden gehecht. Aan posterieure zijde kan het meshimplantaat aan het prerectale weefsel of aan de cervix worden gehecht.

Postoperatief wordt het vaginaweefsel door de VSD ondersteund en bevordert de VSD de druk van de vaginaweefsels tegen het meshimplantaat totdat er weefselingroei plaatsvindt. Gedurende de 3–4 weken na de operatie vindt weefselingroei in het meshimplantaat plaats. Gebruik van het GYNECARE PROSIMA systeem heft de noodzaak van dissectie buiten de bekkenholte op en er hoeven geen hecht draad en instrumenten door de obturatoropening en het sacrospinale ligament te worden gevoerd. Daardoor is de operatie gemakkelijker uit te voeren.

Hysterectomie

Of gelijktijdige uitvoering van hysterectomie gewenst is, wordt bepaald door de voorkeur van de chirurg en door de behoeften van de patiënt. Wanneer hysterectomie wordt verricht, is het raadzaam het cavum Douglas te sluiten, zodat het meshimplantaat niet met de darmen in aanraking kan komen. Sluiting met een "T"-vormige incisie moet worden vermeden, aangezien het risico van blootlegging van het meshimplantaat wordt vergroot. Wanneer gelijktijdig met anterieure en/of posterieure reparatie vaginale hysterectomie wordt verricht, moet de hysterectomie-incisie eerst transversaal worden gesloten. Vervolgens moeten de reparatie-incisies zodanig worden gemaakt dat zij niet met de eerder gesloten hysterectomie-incisie in aanraking komen. De reden hiervan is, te voorkomen dat er een "T"-vormige incisie ontstaat.

Conservatieve uteruschirurgie

Het GYNECARE PROSIMA systeem is geschikt voor gebruik in situaties waarbij de chirurg of de patiënt de uterus wil sparen.

Vaginale incisies

De vaginale incisies die bij de procedure met het GYNECARE PROSIMA systeem worden verricht zijn gelijk aan de incisies die de chirurg bij standaard vaginareparatie maakt. De gehele diepte van de vaginawand moet door de incisies worden doorsneden, om het risico van blootlegging van de mesh te verminderen.

Plaatsing van het meshimplantaat

De meshimplantaten worden door de VSO op hun plaats gefixeerd gehouden totdat er weefselingroei plaatsvindt. Daarom is fixeren van de bandjes van het meshimplantaat niet nodig. Het apicale gedeelte van het meshimplantaat kan aan de fascia in het midden van de apex vaginae worden gehecht met een hecht draad zoals 2-0 MONOCRYL™ (Poliglecapron 25) of 2-0 Coated VICRYL™ (Polyglactine 910). Het vagina-epitheel mag niet op het meshimplantaat worden gehecht.

Vaginabehoud

Er mag niet te veel vagina-epitheel worden geëxideerd of anderszins verwijderd. Postoperatief kan enige weefselretractie plaatsvinden en de vermindering van vaginacapaciteit kan verslechteren als er te veel vagina-epitheel is verwijderd.

Vaginaondersteuning op drie niveaus

In de gangbare methoden voor vaginale ondersteuning bij vaginareparatie worden 3 niveaus onderscheiden. Door het GYNECARE PROSIMA systeem in een procedure te gebruiken wordt beoogd deze ondersteuning te verschaffen op de niveaus I en II, als volgt te definiëren:

Niveau I – Suspensie en ondersteuning (bovenste eenderde deel van de vagina)

Het bovenste eenderde deel van de vagina (inclusief het door hysterectomie ontstane gewelf) en de uterus worden door 2 mechanismen ondersteund. Directe ondersteuning van de uterus en het bovenste deel van de vagina wordt in de eerste plaats verschaft door het parametrium (ligamentum cardinale en uterosacrale) en de paracolpiumvezels. Deze vezels doen dienst als steunligament en komen voort uit de fascia van de m. piriformis, het sacro-iliacale gewricht en het laterale sacrum, en steken uit in het lateraal-bovenste eenderde deel van de vagina en het posterolaterale vlak van de cervix. In de tweede plaats wordt indirecte ondersteuning van de uterus het bovenste deel van de vagina verschaft door de levatorplaat, die wordt gevormd door fusie van de rechter en linker mm. levator ani tussen het rectum en het os coccygis. Als gevolg van falen van deze directe en indirecte steunmechanismen kan prolaps van uterus en vaginagewoefsel optreden. De kans is groot dat dit gepaard gaat met verzwakking van de musculaire bekkenbodem en de steunvezels van het parametrium en het bovenste paracolpium. Het doel van prolapschirurgie op niveau I is de directe en indirecte steunmechanismen te herstellen. Met het GYNECARE PROSIMA systeem worden bij anterieure vaginareparatie meshimplantaatbandjes tegen elk van de mm. obturatorius internus en de daarboven liggende parietale fascia gelegd, en bij posterieure vaginareparatie worden meshimplantaatbandjes tegen de sacrospinale ligamenten gelegd. Dit verschaft het bovenste deel van de vagina en de uterus directe ondersteuning door suspensie en indirecte ondersteuning door een brede zone van meshimplantaatsteun.

Niveau II – Laterale bevestiging (middelste eenderde deel van de vagina)

Het middelste deel van de vagina wordt door de arcus tendineus fasciae pelvis (ATFP) lateraal en direct met de spieren van de bekkenzijwand verbonden. Op dit niveau strekken de anterieure en posterieure vaginawanden zich uit tussen de laterale bevestigingen links en rechts. Prolapsreparatie op niveau II heeft als doel het laterale middelste gedeelte van de vagina opnieuw op de spieren van de bekkenzijwand te hechten. Bij centrale defecten van het middelste deel van de vagina is ook ondersteuning op niveau II nodig. Het gebruik van het GYNECARE PROSIMA systeem in een procedure herstelt laterale bevestiging van de vagina op de bekkenzijwandspieren en biedt tevens centrale fasciaversterking nadat weefselingroei heeft plaatsgevonden.

Niveau III – Fusie (onderste eenderde deel van de vagina)

OPMERKING: Bij het GYNECARE PROSIMA systeem is losprepareren in dit gedeelte niet nodig.

Bij reparatie op niveau III wordt het onderste eenderde deel van de vagina anterieur met het perineale membraan en de urethra samengevoegd. Posterieur fuseert het onderste eenderde deel van de vagina met het perineum en de mm. levator ani. De weefsels in deze zone worden zonder meshimplantaat geprepareerd; het meshimplantaat is niet bedoeld voor gebruik in het onderste eenderde deel van de vagina. Met het GYNECARE PROSIMA systeem worden geen ondersteuningsdefecten van niveau III behandeld, al kunnen deze wel worden aangepakt met concomitante procedures zoals penneurrafie.

DEEL 3: GEBRUIKSAANWIJZING

OPMERKING: Bij lezing van dit gedeelte wordt verwezen naar de afbeeldingen in het begin van dit document.

Operatievoorbereiding

Chirurgie met het GYNECARE PROSIMA systeem kan worden verricht onder algehele of regionale anesthesie, afhankelijk van de voorkeur van chirurg, anesthesioloog en patiënt.

De patiënt moet in steensnedeligging worden gelegd, met de billen enigszins over de operatietafelrand en de heup in flexie. Naar keuze van de chirurg kan de blaas worden geleegd. Voorafgaand aan het vullen van de ballon moet een katheter worden geplaatst.

Gebruik van GYNECARE PROSIMA systeem in procedures na hysterectomie

Anterieure vaginareparatie

Wanneer alleen de anterieure vaginawand moet worden versterkt, kan uitsluitend het GYNECARE PROSIMA anterieure bekkenbodemreparatiesysteem worden gebruikt. Dit systeem bevat 1 meshimplantaat en een speciaal ontworpen anterieur inbrenginstrument voor toepassing bij een anterieure vaginareparatie. Na verrichting van de benodigde vaginale incisies en dissecties worden weefselkanalen in het anterieure compartiment gemaakt, waarin met het anterieure inbrenginstrument de meshimplantaatbandjes worden geplaatst. **OPMERKING: Het inbrenginstrument anterieur dient niet gebruikt te worden voor het losprepareren van weefsel.**

Anterieure vaginale dissectie

Dissecteer het anterieure vagina-epitheel van de blaas. Dissecteer de gehele dikte van de vaginawand. Deze dissectie moet worden vergemakkelijkt door subepitheliale hydrodissectie. Vermijd oppervlakkige dissectie van de vaginawand of kleving van de vaginawand in 2 lagen. Een dergelijke wijze van dissecteren kan een zeer dunne vaginawand tot gevolg hebben en kan ook de bloetoevoer naar de vaginawand verslechteren, waardoor het risico van blootlegging van mesh groter wordt. Lateraal wordt het losprepareren in de richting van de bekkenzijwand voortgezet, tot de spina ischiadica.

Het anterieure kanaal losprepareren en het meshimplantaat plaatsen

Voor om het doel van deze beschrijving te bereiken het losprepareren voor het maken van kanalen voor de meshimplantaatbandjes eerst aan de rechterzijde van de patiënt uit en daarna aan de linkerzijde. Het doel van deze kanalen is, het meshimplantaat zodanig te plaatsen dat het distale gedeelte van de bandjes effen tegen de bekkenzijwand en de parietale fascia van de m. obturatorius internus ligt. Begin het losprepareren voor het plaatsen van de bandjes met palperen om aan beide zijden de spina ischiadica te lokaliseren. **OPMERKING: Het losprepareren kan ook met een schaar worden begonnen, met toepassing van een "duw-en-spreidetechniek", zodat de punten van de schaar altijd anterieur van de spina ischiadica blijven.** Volg de aanvankelijke dissectie door voorzichtige dissectie met de vinger, tot aan de spina ischiadica. Nadat de spina ischiadica is bereikt, wordt met een vegende beweging van de wijsvinger een holte ruime gemaakt, anterosuperieur van de spina ischiadica. Ze breed en ca. 3 cm hoog. Bij de anterieur dissectie is geen sprake van dissectie op de sacrospinale ligamenten. Door deze dissectie wordt een kanaal tot stand gebracht anterosuperieur van de spina ischiadica

en gelijkvloers met de arcus tendineus fasciae pelvis (ATFP), de m. obturatorius internus en de parietale fascia daarvan. Herhaal de dissectie aan de linkerzijde.

Plooiing van het prevesicale weefsel is niet nodig. Wanneer echter wel plooiing wordt uitgevoerd, moet dit beperkt blijven tot het centrale gedeelte van dit weefsel. Zo wordt vermeden dat de gedissecteerde zone te smal wordt. Plaats het meshimplantaat boven het prevesicale weefsel, waarbij de zakjes naar boven wijzen. Wanneer er moet worden gehecht, moet dat op dit proceduremoment worden gedaan: plaats een hecht draad (zoals 2-0 MONOCRYL of 2-0 Coated VICRYL) in de apex vaginae en rijg deze door het apicale lijfje van het meshimplantaat. De hechting kan nu worden afgebonden, of anderszins nadat de bandjes zijn geplaatst. De distale groef van het meshimplantaat kan naar keuze wel of niet worden gehecht; in het eerste geval kan dit worden uitgevoerd met een hecht draad als 2-0 MONOCRYL of 2-0 Coated VICRYL.

Plaats met behulp van het anterieure inbrenginstrument de bandjes van het meshimplantaat in de kanalen rechts en links die zijn aangemaakt door de dissectie anterosuperieur van de spina ischiadica (zoals hierboven beschreven). **OPMERKING: De gebogen uiteinden van het anterieure inbrenginstrument zijn in tegengestelde richtingen gedraaid, en op de uiteinden bevinden zich pijltjes die de plaatsingsrichting aangeven.** Richt het pijltje naar de rechterzijde van de patiënt en breng de tip van het anterieure inbrenginstrument in het zakje van het meshimplantaatbandje aan de rechterzijde van de patiënt (zie afbeelding 8B). **OPMERKING: Door het uitoefenen van tegenactieve kracht blijft het zakje steviger op het anterieure inbrenginstrument geplaatst.** Houd het anterieure inbrenginstrument verticaal, zodanig dat het gebogen gedeelte van het instrument tegen de posterieure vaginawand rust. Voer het anterieure inbrenginstrument, met het bandje erop, vervolgens in het eerder gemaakte weefselkanaal (zie afbeelding 8C) totdat de handgreep in aanraking komt met de labia majora aan contralaterale zijde. Dit wordt uitgevoerd door bovenwaarts-verticale positionering van het handgreepgedeelte van het anterieure inbrenginstrument, zodanig dat de voorrand en het zakje zich in de richting van de spina ischiadica bewegen. Kantel de handgreep na positionering omhoog tot een bijna-horizontale stand en handhaaf daarbij het contact van de handgreep met het contralaterale dijbeen. **OPMERKING: Retractie van de blaas met een standaard chirurgisch instrument kan u helpen bij de eerste plaatsing in het kanaal. Desgewenst kunt u met de wijsvinger in het kanaal de aanvankelijke plaatsing van het anterieure inbrenginstrument tegen de labia majora aan contralaterale zijde geleiden, voordat de handgreep omhoog wordt gekanteld.** Door licht omhoog te drukken kunt u zich ervan verzekeren dat de zakjes goed zijn gepositioneerd en dat het apicale gedeelte van het meshimplantaat tegen de apex vaginae duikt. **OPMERKING: Indien u bij het inbrengen van de bandjes weerstand ondervindt, moet u de oorzaak van de weerstand bepalen voordat u de procedure voortzet. Als het opvoeren van het inbrenginstrument tegen weerstand in wordt voortgezet, kan dat beschadiging van het meshimplantaat tot gevolg hebben, of kan het instrument te ver worden ingebracht, met beschadiging van gevoelige weefselsstructuren als gevolg.**

Verwijder het anterieure inbrenginstrument door de handgreep naar de verticale stand terug te kantelen en het instrument dan terug te trekken, waarbij het bandje in het kanaal achterblijft. **OPMERKING: Breng het eerste bandje volledig in.** **OPMERKING: Indien het anterieure inbrenginstrument uit de operatiezone wordt getrokken voordat het meshimplantaatbandje zijn doellocatie heeft bereikt, moet het bandje worden verwijderd, opnieuw op het instrument geplaatst en opnieuw ingebracht.** Herhaal deze handelingen aan de tegenoverliggende zijde van de patiënt. Keer daartoe het anterieure inbrenginstrument om en breng het uiteinde in het andere zakje, met het pijltje gericht op de linkerzijde van de patiënt. Afbeelding 8D toont de beide geïmplanterde bandjes. **OPMERKING: Vermijd bij plaatsing van het tweede bandje dat het meshimplantaat in beweging komt, en verzeker u ervan dat het meshimplantaat NIET is gedraaid.**

Plaats het hoofdgedeelte van het meshimplantaat losjes op het onderliggende vaginaweefsel. Vermijd vouwen of draaien van het hoofdgedeelte en de bandjes. Het kan nodig zijn het hoofdgedeelte van het meshimplantaat bij te knippen, afhankelijk van de grootte van de vagina en/of de mate van laterale dissectie. Het vagina-epitheel kan worden bijgeknipt, mits er niet te veel van wordt verwijderd. Sluit het epitheel over het meshimplantaat zonder gebruik te maken van gekoppelde hechtdraden (zoals hieronder beschreven; zie afbeelding 8E). Afbeelding 8F toont de uiteindelijke plaatsing van het meshimplantaat in het anterieure compartiment.

OPMERKING: Zorg dat voor en tijdens het sluiten van de vaginale incisies goede hemostase is bereikt.

Sluit de vaginale incisies zonder gekoppelde of 8-vormige hechtdraden. Dit is om devascularisatie van het vagina-epitheel langs de incisie lijnen te voorkomen en erosie van de mesh te verminderen. Voorkeur geniet sluiting van het epitheel in 2 lagen, zodat een relatief dikke hechtingsnaad ter plaatse van de vaginale incisie wordt verkregen. Sluit de diepste laag met een doorlopende subepitheliale niet-gekoppelde hechting met een hecht draad zoals 2-0 MONOCRYL of 2-0 MONOCRYL™ Plus Antibacterieel (Poliglecapron 25). Sluit het epitheel vervolgens met een doorlopende niet-gekoppelde everterende matrashechting met een hecht draad zoals 2-0 Coated VICRYL of 2-0 Coated VICRYL™ Plus (Polyglactine 910) antibacterieel. **OPMERKING: Plaats het meshimplantaat in het bovenste tweederde deel van de vagina en knip het implantaat bij als het verder reikt dan het bovenste tweederde deel.** Voor zover dit nog niet is gedaan, wordt geadviseerd cystoscopie uit te voeren, om letsel van de urinewegen uit te sluiten.

Als keuzemogelijkheid kan sluiting van de vaginawand ook enkellaags worden uitgevoerd. Hiervoor kan een doorlopende, everterende, niet-gekoppelde matrashechting of onderbroken hechtingen van hecht draad zoals 2-0 Coated VICRYL of 2-0 Coated VICRYL Plus worden gebruikt.

Posterieure vaginareparatie

Gebruik wanneer alleen de posterieure vaginawand moet worden versterkt uitsluitend het GYNECARE PROSIMA posterieure bekkenbodemreparatiesysteem. Dit systeem bevat 1 meshimplantaat en een speciaal ontworpen posterieur inbrenginstrument voor toepassing bij posterieure vaginareparatie. Maak na verrichting van de benodigde vaginale incisies en dissecties weefselkanalen in het posterieure compartiment, waarin de meshimplantaatbandjes worden geplaatst. **OPMERKING: Het posterieure inbrenginstrument dient niet gebruikt te worden voor het losprepareren van weefsel.**

Posterieure vagina- en kanaaldissectie

Dissecteer het posterieure vagina-epitheel van het prerectale weefsel. Evenals bij de anterieure vaginawand moet ook nu de gehele dikte van de posterieure vaginawand worden losgeprepareerd. Deze dissectie moet worden vergemakkelijkt door subepitheliale hydrodissectie. Zet de dissectie lateraal voort aan beide zijden van de mm. levator ani ter hoogte van de spina ischiadica. Dissecteer verder door elk van de rectale ligamenten en dissecteer op, maar niet dóór, elk van de sacrospinale ligamenten, zodat kanalen worden aangemaakt waarin de meshimplantaatbandjes zullen worden geplaatst. Zie afbeelding 9A.

Naar wijk keuze kan ook een al bestaande enterocele behandeld worden, maar in dat geval moet de behandeling in deze procedurefase worden uitgevoerd, volgens de methode die de voorkeur van de chirurg geniet.

Als de peritoneale holte tijdens anterieure of posterieure dissectie geopend is, moet deze voor het plaatsen van de mesh gesloten worden.

Posterieure plaatsing van het meshimplantaat

Plooiing van het prerectale weefsel is niet nodig. Wanneer echter wel plooiing van het prerectale weefsel wordt uitgevoerd, moet dit beperkt blijven tot het centrale gedeelte van dit weefsel. Zo wordt vermeden dat de gedisseceerde zone te smal wordt. Plaats het meshimplantaat boven het prerectale weefsel, waarbij de zakjes naar boven wijzen. Wanneer er moet worden gehecht, moet dat op dit proceduremoment worden gedaan: plaats een hecht draad (zoals 2-0 MONOCRYL of 2-0 Coated VICRYL) in de apex vaginæ en rijg deze door het apicale lipje van het meshimplantaat. De hechting kan nu worden afgebonden, of anderszins nadat de bandjes zijn geplaatst. De distale groef van het meshimplantaat kan naar keuze wel of niet worden gehecht; in het eerste geval kan dit worden uitgevoerd met een hecht draad als 2-0 MONOCRYL of 2-0 Coated VICRYL.

Plaats met behulp van het posterieure inbrenginstrument de bandjes van het meshimplantaat in de kanalen rechts en links die zijn aangemaakt door de dissectie in de richting van beide sacrospinale ligamenten (zoals hierboven beschreven). Pak het posterieure inbrenginstrument vast met een rechte naaldhouder/naaldvoeder, zoals weergegeven in afbeelding 98. **OPMERKING: Plaats de tip van de naaldhouder/naaldvoeder in het rechte gegroefde uiteinde van het posterieure inbrenginstrument.** Zorg dat het aangedoten posterieure inbrenginstrument op één lijn ligt met de handgreep van de naaldhouder/naaldvoeder. Steek de tip van het posterieure inbrenginstrument in het bandjeszakje aan de rechterzijde van de patiënt (zie afbeelding 98). Voor het posterieure inbrenginstrument, met het bandje erop, vervolgens in het eerder gemaakte weefselkanaal (zie afbeelding 9C) en houd de handgreep van de naaldhouder/naaldvoeder daarbij verticaal. Breng de gehele lengte van het bandje in het kanaal, zodat het begin van het bandje de bovengrens van de fasciale dissectie bereikt. **OPMERKING: Breng het eerste bandje volledig in. Indien het inbrenginstrument uit de operatiezone wordt getrokken voordat het bandje zijn eindlocatie heeft bereikt, moet het bandje worden verwijderd, opnieuw op het instrument geplaatst en opnieuw ingebracht. OPMERKING: Breng het bandje niet te diep in, omdat dan gevoelige weefselsstructuren schade zouden kunnen oplopen. OPMERKING: Indien u bij het inbrengen van de bandjes weerstand ondervindt, moet u de oorzaak van de weerstand bepalen voordat u de procedure voortzet. Als het opvoeren van het inbrenginstrument tegen weerstand in wordt voortgezet, kan dat beschadiging van het meshimplantaat tot gevolg hebben, of kan het instrument te ver worden ingebracht, met beschadiging van gevoelige weefselsstructuren als gevolg.** Trek het posterieure inbrenginstrument terug over het insertietraject, zodanig dat het bandje in het kanaal blijft. De bandjes liggen tegen de sacrospinale ligamenten, maar penetreren deze niet. Plaats geen hechtingen in de sacrospinale ligamenten. Herhaal de procedure aan de linkerzijde van de patiënt met het tweede bandje. Afbeelding 9D toont de beide geïmplanteerde bandjes. **OPMERKING: Vermijd bij plaatsing van het tweede bandje dat het meshimplantaat in beweging komt, en verzeker u ervan dat het meshimplantaat NIET is gedraaid.**

Plaats het hoofdgedeelte van het meshimplantaat losjes op de onderliggende vaginale fascia. Vermijd vouwen of draaien van het hoofdgedeelte en de bandjes van het meshimplantaat. Het kan nodig zijn het hoofdgedeelte van het meshimplantaat bij te knippen, afhankelijk van de grootte van de vagina en/of de mate van laterale dissectie. Het epitheel van de posterieure vaginawand kan worden bijgeknipt, mits er niet te veel van wordt verwijderd. Sluit het epitheel van de posterieure vaginawand over het meshimplantaat zonder gebruik te maken van gekoppelde hecht draden (zoals hieronder beschreven). Afbeelding 9E toont de uiteindelijke plaatsing van het meshimplantaat in het posterieure compartiment.

OPMERKING: Zorg dat voor en tijdens het sluiten van de vaginale incisie goede hemostase is bereikt.

Sluit de vaginale incisie zonder gekoppelde of 8-vormige hecht draden. Dit is om devascularisatie van het vaginale epitheel langs de indolijnen te voorkomen en erosie van de mesh te verminderen. Voorkeur geniet sluiting van het epitheel in 2 lagen, zodat een relatief dikke hechtingsnaad ter plaats van de vaginale incisie wordt verkregen. Sluit de diepste laag met een doorlopende subepitheliale niet-gekopplede hechting met een hecht draad zoals 2-0 MONOCRYL of 2-0 Coated VICRYL Plus antibacterieel. Sluit het epitheel vervolgens met een doorlopende niet-gekopplede everterende matrashechting met een hecht draad zoals 2-0 Coated VICRYL of 2-0 Coated VICRYL Plus. **OPMERKING: Plaats het meshimplantaat in het bovenste tweede deel van de vagina en knip het implantaat bij als het verder reikt dan het bovenste tweede deel.** Bij voltooiing van de procedure moet digitaal rectaal onderzoek worden verricht om letsel van het rectum uit te sluiten.

Als keuzemogelijkheid kan sluiting van de vaginawand ook enkellaags worden uitgevoerd. Hiervoor kan een doorlopende, everterende, niet-gekopplede matrashechting of onderbroken hechtingen van hecht draad zoals 2-0 Coated VICRYL of 2-0 Coated VICRYL Plus worden gebruikt.

Gecombineerde anterieure en posterieure vaginaparaat

Wanneer zowel de anterieure als de posterieure vaginawand moeten worden versterkt, wordt het GYNECARE PROSIMA gecombineerde bekkensbodemparaatsysteem gebruikt. Dit systeem bevat 2 identieke meshimplantaten, één voor de anterieure vaginaparaat en de tweede voor de posterieure vaginaparaat. Gebruik voor anterieure reparaties uitsluitend het gebogen anterieure inbrenginstrument en voor posterieure reparaties uitsluitend het rechte posterieure inbrenginstrument. Voer de anterieure en posterieure vaginaparaaties uit zoals hierboven is beschreven. Geadviseerd wordt, de anterieure vaginaparaat als eerste uit te voeren. De uiteindelijke plaatsing van meshimplantaten in het anterieure en het posterieure compartiment is in afbeelding 10 weergegeven. Het is aan te bevelen, bij voltooiing van de procedure cystoscopie uit te voeren, om letsel van de urinewegen uit te sluiten. Om letsel van het rectum uit te sluiten moet digitaal rectaal onderzoek worden verricht.

Gebruik van GYNECARE PROSIMA systeem met behoud van de uterus (hysteropexie)

Indien de geprolabeerde uterus wordt behouden, moet het apicale lipje van het meshimplantaat op de cervix worden gefixeerd. Het meshimplantaat moet ter hoogte van de pubocervicale ring op de cervix worden gefixeerd wanneer het implantaat tijdens de anterieure of posterieure vaginaparaat is aangebracht.

Wanneer de uterus bij anterieure vaginaparaat wordt behouden, wordt de pubocervicale ring tijdens de anterieure vaginale dissectie blootgelegd. Plaats een 2-0 PROLENE hechting stevig in het anterieure segment van de pubocervicale ring. Rijg deze hechting ook door het apicale lipje van het meshimplantaat. Knoop de PROLENE hechting op het lipje af nadat de bandjes van het meshimplantaat zijn gepositioneerd. Hierdoor wordt het meshimplantaat ter hoogte van de pubocervicale ring op het anterieure oppervlak van de cervix vastgezet en wordt gewaarborgd dat het meshimplantaat de uitzetting van de vagina volgt als de VSD op de juiste wijze is gepositioneerd.

Bevestig bij de posterieure paraat het meshimplantaat aan de posterieure cervix ter hoogte van of hoger dan de pubocervicale ring. Desgewenst kan het cavum Douglasi geopend blijven terwijl het meshimplantaat aan de cervix wordt gefixeerd. Sluit het peritoneum van het cavum Douglasi boven deze hechting, zodat adhesie van de darmen aan het meshimplantaat wordt verhinderd. Als de chirurg besluit het cavum Douglasi niet te openen, wordt de pubocervicale ring tijdens de posterieure vaginale dissectie blootgelegd. Plaats een 2-0 PROLENE-hechting stevig in het posterieure segment van de pubocervicale ring. Rijg deze hechting ook door het apicale lipje van het meshimplantaat. Knoop de PROLENE-hechting af nadat de bandjes van het meshimplantaat zijn gepositioneerd. Hierdoor wordt het meshimplantaat ter hoogte van de pubocervicale ring op het posterieure cervixoppervlak vastgezet.

Wanneer voor zowel anterieure als posterieure vaginaparaat meshimplantaten worden gebruikt, moeten de implantaten op de hierboven beschreven wijze aan de anterieure en posterieure segmenten van de cervix worden bevestigd (zie afbeelding 11).

Hygiëne maatregelen m.b.t. het meshimplantaat

Irrigeer tijdens de chirurgische procedure de vaginale operatiewonden met fysiologisch-zoutoplossing. Beperk de manipulatie van het meshimplantaat tot een minimum en voer de operatie onder goede hygiënische condities uit.

De VSD en de ballon plaatsen

Breng bij voltooiing van de operatie een VSD (Vaginal Support Device, vaginasteun) van geschikt formaat met een daaraan bevestigde ballon in de vagina in, en hecht deze om losraken van het implantaat te voorkomen. De VSD is in 3 maten verkrijgbaar (small, medium en large) en kan op de hieronder beschreven wijze door de chirurg aan de vaginallengte van de patiënt worden aangepast.

Passen en bijsnijden van de VSD

De VSD wordt in de grootste maat geleverd. Bepaal met behulp van de VSD zelf de passende maat voor de patiënt. Breng hiertoe de 'large' VSD in de vagina in, tussen de uitgezette apex en de hymenring. Breng de VSD in de vagina in door de VSD op het breedste deel vast te pakken en langs de lengteas te vouwen, met de ballon naar boven gericht (zie afbeelding 12). Het breedste gedeelte van de VSD wordt het eerst ingebracht, zodat de hechtopeningen zich net boven de hymenring bevinden. **OPMERKING: Verwijder of beschadig de ballon niet tijdens het passen van de VSD.** Het juiste formaat is bereikt wanneer de VSD sluitend in het bovenste tweede deel van de uitgezette vagina past, met het distale uiteinde en de hechtgootjes 1 cm boven de hymenring (zie afbeelding 13).

Als de maat 'large' past, hoeft de VSD niet te worden aangepast. Als de maat 'medium' benodigd blijkt, moet het bovenste gedeelte worden verwijderd. Doe dit door voorzichtig kleine fragmentjes te knippen, uitsluitend gebruikmakend van de tips van een gebogen Mayo-schaar, zodat een gladde snijrand ontstaat. Zorg dat de hoeveelheid restmateriaal van de alknipszones tot een minimum beperkt blijft. **OPMERKING: Zorgvuldige passing van de VSD is van groot belang. Nadat een VSD is bijgeknipt, kan hij niet meer langer worden gemaakt en kunnen de afgeknipte deeltjes niet meer worden teruggezet.** Verplaats tijdens het knippen de ballon zodanig dat hij niet in de weg zit (zie afbeelding 14). **Waak ervoor dat de ballon tijdens het bijknippen van de VSD zou worden beschadigd.**

Als de maat 'medium' past, hoeft de VSD niet te worden bijgeknipt. Als de maat 'small' moet worden gebruikt, moet het overblijvende gedeelte worden verwijderd, zoals hierboven is beschreven. Verplaats tijdens het knippen de ballon om beschadiging te voorkomen.

Na goede passing van de VSD en terugplaatsing van de ballon kan de VSD-constructie in de vagina van de patiënt worden ingebracht. **OPMERKING: Om het risico van perforatie van de ballon te verkleinen mogen bij het inbrengen van de VSD of de ballon geen instrumenten worden gebruikt.** Bij beschadiging van de ballon moet deze van de VSD worden losgemaakt en moet de vaginaholte met een gazen kompres sluitend worden gevuld.

Fixeer de VSD met hecht draad nadat de VSD/ballonset op de juiste positie in het bovenste tweede deel van de uitgezette vagina van de patiënt is geplaatst: één enkele slag door elk hechtgootje van de VSD, vervolgens in het epitheel van de posterieure vaginawand en aan beide zijden lateraal en van boven het hymen in 4- en 8-uursposities, zoals weergegeven in afbeelding 15. Knoop de hechtingen links en rechts vervolgens beurtelings af en houd daarbij de VSD in de vagina stabiel in positie. **OPMERKING: Let op dat u de ballon niet puncteert bij het in positie hechten van de VSD.** Voor deze toepassing wordt 2-0 gecoat Coated VICRYL hecht draad of een gelijkwaardig resorberebare hecht draad aanbevolen.

De ballon vullen

Sluit nadat u de VSD in positie hebt gehecht de bijgeleverde 50 ml spuit aan. **OPMERKING: Na het plaatsen van de VSD moet een katheter worden geplaatst om urineretentie te voorkomen.** Spuit een kleine hoeveelheid omgevingslucht in (zie afbeelding 16) en palpeer vervolgens de gehele lengte van de ballon met een vinger om te controleren of de ballon is ontvouwen en over de gehele lengte van de vagina is geplaatst. Neem de vinger weg wanneer vastgesteld is dat de ballon is ontvouwen en vul de ballon geheel, totdat een vingertop bij de vaginaingang nog net tussen de ballon en de vaginawand past. Het is raadzaam de VSD tijdens het opblazen van de ballon te stabiliseren. De functie van de gevulde ballon is, het meshimplantaat tegen de vaginawand te drukken. De voor het vullen van de ballon benodigde hoeveelheid lucht verschilt van patiënt tot patiënt. **OPMERKING: De ballonvulling mag de maximumwaarde van 90 ml niet overschrijden.** Draai de spuit los van de afsluiter nadat de ballon voldoende is gevuld. De vullijn van de ballon moet uit de vagina naar buiten steken en wordt tegen het dijbeen van de patiënt geplakt. Maak de dop vast op de afsluiter van de ballon, zodat gewaarborgd is dat de beoogde hoeveelheid lucht in de ballon constant blijft (zie afbeelding 7). **OPMERKING: Draai de dop niet te strak vast.** Zo nodig moet de ballonvulling op een later tijdstip kunnen worden aangepast, door het ballonvolume met een standaard spuit te vergroten of te verkleinen. De ballon kan op willekeurige momenten worden geïmpaleerd of met het oog geïnspecteerd om zeker te stellen dat de vulling nog toereikend is. **OPMERKING: Als de patiënt beweegt, kan de ballon zich in de vaginaholte vastzetten en kan de druk schijnbaar hoger of lager worden. Dit is normaal.**

OPMERKING: Maak de ballon niet los van de VSD voordat de set wordt gebruikt.

OPMERKING: Vul de ballon niet voordat hij in de vagina wordt ingebracht.

OPMERKING: Als de hechtgootjes van de VSD na het vullen van de ballon zijn verschoven tot meer dan 1 cm boven de hymenring, of als er bovenmatige spanning op de hechtgootjes wordt uitgeoefend, moet de ballondruk worden verminderd en moet, zo nodig, de VSD opnieuw worden gepositioneerd en gepast.

OPMERKING: Als er gaten in de ballon zichtbaar zijn of als er anderszins lekkage wordt gedetecteerd, of als de ballon na het vullen druk verliest, moet u de ballon NIET gebruiken. Maak de ballon dan los van de VSD en voer hem conform de daarvoor geldende voorschriften af. Gebruik dan in plaats van de ballon een gazen kompres.

OPMERKING: Als het aansluitstuk van de ballon van de VSD losraakt, moet het op zijn plaats worden teruggevoerd.

OPMERKING: Fixeer de ballonvullijn niet in de vagina.

OPMERKING: Om beschadiging te voorkomen mag de vullijn nooit aan overmatige buiging, spanning of torsie worden blootgesteld.

OPMERKING: Gebruik geen gazen kompres als er al een ballon is geplaatst.

De ballon van de VSD losmaken

Verwijder 1 dag postoperatief de ballon na volledige ontluchting met behulp van een standaard spuit. De VSD blijft hierbij in situ. **OPMERKING: Laat de ballon niet langer dan 1 dag in de vagina.**

1) Neem de dop van de ballonaafsluiter.

2) Sluit een standaard 50 ml (of grotere) spuit aan op de ballonaafsluiter en ontluicht de ballon geheel (zie afbeelding 17). Het is van belang dat de ballon geheel leeg is voordat hij van de VSD wordt losgemaakt. **OPMERKING: De ballon is geheel leeg als de zuiger in de spuit wordt teruggetrokken nadat alle lucht is verwijderd.**

3) Maak de spuit los.

4) Daarna kan de ballon van de VSD worden losgemaakt en uit het lichaam van de patiënt worden verwijderd: trek voorzichtig in caudale richting aan de vullijn, op een locatie dicht bij de ballonaafsluiter en oefen tegelijkertijd met een vinger voorzichtig tegenactie uit op het distale uiteinde van de VSD. Zie afbeelding 18.

OPMERKING: Trek de ballon pas terug als hij geheel is ontluicht en als er geen weerstand voelbaar is. Als er wel weerstand optreedt, moet u de oorzaak daarvan bepalen voordat u de procedure voortzet. Voortzetting van het inbrengen of terugtrekken van de ballon tegen weerstand in kan tot gevolg hebben dat de VSD wordt verplaatst en/of dat het weefsel van de vaginahalve letsel oploopt. Overtuig u ervan dat de ballon geheel is ontluicht door de spuit weer aan te sluiten en alle lucht te verwijderen voordat u doorgaat met verwijderen.

De VSD uit het lichaam van de patiënt verwijderen

Verwijder de VSD uit het lichaam van de patiënt, ongeveer 3 tot 4 weken na de operatie, nadat zich afdoende genezing heeft gerealiseerd. Tegen de tijd kunnen de resorbabele hechtingen zijn opgelost of hebben zij voldoende aan treksterkte ingeboet om probleemloze verwijdering van de VSD, zonder weerstand van hechtmateriaal, mogelijk te maken. **OPMERKING: Het kan nodig zijn, de beide hechtingen door te knippen om de VSD te kunnen verwijderen. OPMERKING: Laat de VSD niet langer dan 4 weken in de vagina.** Verwijder alle restjes VSD-hechtmateriaal. Verwijder de VSD met de hand uit het vaginakanaal, zoals in afbeelding 19 wordt getoond.

Perioperatieve zorg

Al naar gelang de gebruikelijke praktijkmethoden van de chirurg kunnen patiënten profylactische antibiotica krijgen. Afhankelijk van de voorkeur van de chirurg kan het geven van antibiotica postoperatief worden voortgezet. Ook kunnen trombo-embolische profylactica worden ingezet.

De chirurg dient uit te leggen wat het doel is van de VSD, die tot vier weken na de operatie in de vagina blijft: het ondersteunen van de vagina tegen de mesh tijdens de genezingsperiode. De patiënt moet ervan in kennis worden gesteld dat de VSD zal worden verwijderd tijdens een postoperatieve controle, ongeveer 4 weken na de operatie. De patiënt moet ervan in kennis worden gesteld dat postoperatieve vaginale afscheiding te verwachten is en dat de VSD iets omhoog kan komen. Wanneer de patiënt merkt dat de VSD omhoog gekomen is, kan zij deze voorzichtig omhoog duwen tot in een meer comfortabele positie. Wanneer echter de VSD aanzienlijk ongemak veroorzaakt, dient de patiënt te worden geadviseerd contact op te nemen met haar arts.

Na ontslag uit het ziekenhuis moet de patiënt worden geïnstrueerd gedurende 3 tot 4 weken inspannende lichamelijke activiteiten te vermijden. Na die periode zullen de bekkenweefsels zich met het meshimplantaat hebben verweven en kan de patiënt de normale dagelijkse activiteiten hervatten. De patiënt moet worden geadviseerd zich gedurende ten minste 6 weken na de operatie te onthouden van seksuele gemeenschap. Op elk moment na de operatie kunnen bekkenbodem oefeningen aanbevolen worden.

WERKINGSEIGENSCHAPPEN

Onderzoek bij proefdieren toont aan dat implantatie van een GYNECARE GYNEMESH PS een minimale tot lichte ontstekingsreactie opwekt, die van voorbijgaande aard is en wordt gevolgd door afzetting van een dun laagje bindweefsel dat door de openingen in de mesh kan groeien, zodat de mesh in het naastliggende weefsel wordt opgenomen. De mesh blijft zacht en buigzaam en de normale wondgenezing wordt niet merkbaar belemmerd. Het materiaal wordt niet geresorbeerd en is evenmin onderhevig aan afbreking of verzakking door de werking van weefselenzymen.

CONTRA-INDICATIES

- Als GYNECARE GYNEMESH PS wordt gebruikt bij zuigelingen, kinderen, zwangere vrouwen of vrouwen die in de toekomst nog zwanger willen worden, moet de chirurg zich ervan bewust zijn dat de mesh niet noemenswaardig zal meerekken bij groei van de patiënt.
- Het GYNECARE PROSIMA systeem mag niet worden uitgevoerd als er sprake is van zwangerschap, etervormende infecties of kanker van de vagina, cervix of uterus.

WAARSCHUWINGEN EN VOORZORGSMAATREGELEN

- Gebruikers dienen vertrouwd zijn met de chirurgische procedures en technieken samenhangend met reconstructie van de bekkenbodem en met niet-resorbabele meshes voordat GYNECARE PROSIMA systemen worden gebruikt.
- Het gebruik van het GYNECARE PROSIMA systeem is niet volledig geëvalueerd voor patiënten met bekkenorgaanprolaps in stadium IV. Gebruik bij deze patiënten wordt daarom afgeraden.
- Voor procedures met het GYNECARE PROSIMA systeem moeten aanvaarde chirurgische methoden worden toegepast, evenals voor de behandeling van geïnfecteerde of verontreinigde wonden.
- Gebruik het GYNECARE PROSIMA systeem niet indien er verdenking bestaat van infectie of besmetting van het te behandelen gebied. Als het meshimplantaat en/of de VSD/ballonset worden gebruikt in besmette gebieden, moet u er rekening mee houden dat bij een eventuele infectie verwijdering noodzakelijk kan zijn.
- De patiënt moet worden geadviseerd gedurende 3 à 4 weken na de operatie geen zware voorwerpen te tillen en/of andere lichamelijke inspanningen te verrichten (b.v. fietsen of joggen), en zich 6 weken te onthouden van seksuele gemeenschap, of totdat de arts het verantwoord acht dat de patiënt haar normale activiteiten hervat.
- Laat de VSD niet langer dan 4 weken in de vagina.
- Laat de ballon niet langer dan 1 dag in de vagina.
- De componenten van het GYNECARE PROSIMA systeem zijn niet bedoeld voor gebruik in combinatie met andere hulpmiddelen dan de in deze bijsluiting vermelde hulpmiddelen.
- Vermijd dat er tijdens de plaatsing overmatige druk- of trekspanning op het meshimplantaat wordt uitgeoefend.
- Gebruik GYNECARE PROSIMA systemen voorzichtig en houd rekening met de anatomische kenmerken van de patiënt, zodat beschadiging van bloedvaten, zenuwen, blaas, darmen en perforatie van de vaginawand worden vermeden. Een correct gebruik van de componenten van het GYNECARE PROSIMA systeem minimaliseert de risico's.
- Vul de ballon uitsluitend met omgevingslucht.
- Bevestig door middel van palpatie na het vullen dat de ballon niet lekt. De effectiviteit van de ballon wordt beperkt door volledige ontluchting.
- De ballonwand is dun, zodat de gewenste eigenschappen van de ballon worden gerealiseerd. Door lekken, sneden, keegies, kreukeling of overspanning van de ballon kan vulvolume verloren gaan. De ballon kan gemakkelijk worden gepneetreed door naalden of scalpels, of gescheurd door manipulatie met stompe instrumenten. Ga bij het hanteren van de ballon voorzichtig te werk om dergelijke beschadigingen te voorkomen. Een beschadigde ballon mag niet worden gebruikt. Verwijder de ballon in zo'n geval en tamponneer de vagina met een gaas kompres.

- De ballon kan maximaal 90 ml bevatten. Overvul de ballon niet. Overmatige vulling van de ballon kan de patiënt ongemak opleveren, kan oorzaak zijn van weefselnecrose, postoperatieve scheuring van de vaginawond en kan het ontluichten van de ballon verhinderen.
- Gebruik GYNECARE PROSIMA systemen niet bij patiënten die met anticoagulantia worden behandeld.
- Er kan postoperatieve bloeding optreden. Controleer of hiervan symptomen of indicaties waarneembaar zijn voordat de patiënt uit het ziekenhuis wordt ontslagen.
- De patiënt moet worden geïnstrueerd, onmiddellijk met de chirurg contact op te nemen als er sprake is van ongewone pijn, bloeding of andere problemen.
- Hoewel de kans op blaasletsel bij deze techniek gering is, wordt geadviseerd cystoscopie uit te voeren.
- Hoewel de kans op rectaal letsel bij deze techniek gering is, dient digitaal rectaal onderzoek te worden uitgevoerd.
- Bevestig het GYNECARE GYNEMESH PS meshimplantaat niet met behulp van staples, clips of klemmetjes, aangezien het implantaat daardoor mechanische schade kan oplopen.
- Het meshimplantaat mag zich niet in het onderste eenderde deel van de vagina bevinden. Knip het meshimplantaat zo nodig bij tot het overgangspunt tussen het onderste en het middelste eenderde deel van de vaginawand.
- Al naar gelang de gebruikelijke praktijkmethoden van de chirurg kunnen profylactische antibiotica worden toegediend.

BIJWERKINGEN

- Mogelijke ongewenste reacties zijn de bij chirurgisch implanteerbare materialen gangbare reacties, zoals verhoogde infectiekans, ontsteking, vorming van adhesies, vorming van fistels, erosie, uilstoting van het implantaat en contractie van het implantaat als gevolg van littekenvorming.
- Ook kunnen de bij reparatie van bekkenorgaanprolaps gangbare reacties voorkomen, zoals pijn bij geslachts-gemeenschap en bekkenpijn. Deze klachten verdwijnen vaak na verloop van tijd vanzelf.
- Tijdens het dissecceren of het plaatsen van het meshimplantaat kunnen zich lekken of laceraties of andere letsels van bloedvaten, zenuwen, blaas, urethra of darmen voordoen. Dit vergt mogelijk operatieve reparatie.
- Bij het dissecceren voor bekkenbodemreparatieprocedures bestaat de kans op verslechtering van de normale mictie gedurende een periode die in lengte kan variëren.

STERILITEIT

De GYNECARE PROSIMA systemen zijn met ethyleenoxide gesteriliseerd. Steriliseer elementen van het GYNECARE PROSIMA systeem NOOIT OP NIEUW. Elementen van het GYNECARE PROSIMA systeem mogen NIET WORDEN HERGEBRUIKT. Opnieuw gebruiken van dit instrument (of onderdelen hiervan) kan een risico van productafbraak en kruisbesmetting veroorzaken, hetgeen kan leiden tot overdracht van bloed-overdraagbare pathogenen aan patiënten en gebruikers. Niet gebruiken als de verpakking beschadigd of geopend is. Werp onderdelen van het GYNECARE PROSIMA systeem waarvan de verpakking geopend is altijd weg, ook als het instrument niet is gebruikt.









AFVOEREN

Voer de componenten en verpakkingsmaterialen van het GYNECARE PROSIMA systeem af volgens de in uw instelling geldende beleidslijnen en procedures met betrekking tot biologisch gevaarlijk materiaal en afval.

OPSLAG

Aanbevolen opslagomstandigheden: regelbare kamertemperatuur en relatieve luchtvochtigheid (temperatuur ca. 25 °C, relatieve luchtvochtigheid 60 %), op veilige afstand van vocht en directe hitte. Gebruik het systeem niet na de uiterste gebruiksdatum.

Op etiketten en in productdocumentatie gebruikte symbolen

	
0086 CE-markering en identificatienummer van instantie van aanmelding. Het product voldoet aan de essentiële eisen van de Richtlijn betreffende medische hulpmiddelen 93/42/EEG.	Fabrikant
	
Lotnummer	Niet opnieuw gebruiken of opnieuw steriliseren
	
Uiterste gebruiksdatum: --- jaar en maand	Zie de gebruiksaanwijzing
	
STERILE	Sterilisatiemethode --- ethyleenoxide



Anteriorinen lantionpohjan korjausjärjestelmä
Posteriorinen lantionpohjan korjausjärjestelmä
Yhdistetty lantionpohjan korjausjärjestelmä

Lue kaikki ohjeet huolellisesti.

Ohjeiden laiminlyönti saattaa johtaa laitteiden virheelliseen toimintaan ja potilasvahinkoon.

HUOMIO: Yhdysvaltain lain mukaan tämän tuotteen saa myydä ainoastaan lääkäri tai lääkärin määräyksestä.

Lantionpohjan GYNECARE PROSIMA™ -korjausjärjestelmien käyttöön tutustuminen on suositeltua ja koulutusta tähän tarkoitukseen on järjestettävissä. Lisätietoja koulutusohjelmasta saa yhtön myyntiedustajalta.

KÄYTTÖTARKOITUS

Lantionpohjan GYNECARE PROSIMA -korjausjärjestelmät ja niiden kanssa käytettävät resorbittomattomat GYNECARE GYNEMESH™ PS Soft Mesh PROLENE™ -verkkokomplantit on tarkoitettu käytettäväksi kudoksen vahvistamiseen ja pitkäaikaiseen lantionpohjan sidekudoserakenteiden stabilointiin joko mekaanisena tukena tai faskiadefektin tukimateriaalina. Järjestelmät mahdollistavat emätinkanavan tukemisen parantumisprosessin aikana emättimen seinämän laskeuman kirurgisen korjaustoimenpiteen jälkeen tukeen samalla verkkokomplanttien sijaintikohtaa.

KUVAUS

Anteriorinen, posteriorinen ja yhdistetty lantionpohjan GYNECARE PROSIMA -korjausjärjestelmä koostuu valmiiksi leikattusta GYNECARE GYNEMESH PS -verkkokomplantista ja instrumenteista, jotka helpottavat verkkokomplantin asettamista ja leikkauksenjälkeistä tukemista (kuva 1). Seuraavassa taulukossa on yhteenveto eri järjestelmien mukana toimitettavista komponenteista:

LANTION- POHJAN KORJAUSJÄR- JESTELMÄ	KOMONENTIT (kuva 1)				
	Verkkokomplantti asettimessa (A)	Emätintuki – Padokokoosnaru (B ja C)	Anteriorinen sisäänviejä (D)	Posteriorinen sisäänviejä (E)	Ruisku (F)
Anteriorinen	1	1	1		1
Posteriorinen	1	1		1	1
Yhdistetty	2	1	1	1	1

Taulukko 1 --- Lantionpohjan GYNECARE PROSIMA -korjausjärjestelmän komponentit

GYNECARE GYNEMESH PS

GYNECARE GYNEMESH PS -verkko on valmistettu puustetusta polypropyleeni-eleukudoksesta, joka on koostumuksestaan samanaikainen kuin resorbittomattomat kirurgiset PROLENE™-polypropyleeniomelaineet. (ETHICON, INC.). Tämän materiaalin ei ole todettu onnellankana käytettäessä aiheuttavan kudoserakkeita ja se pysyy kliinisessä käytössä pysyvästi muuttumattomana. Verkko on erittäin vahva, kestävä ja kirurgisesti monikäyttöinen, ja se on riittävän huokoisen kudokasvulle. Verkkoon on lisitty sinisiä, yksi-säikeisiä PROLENE -suituja kontrastiraidituksen alkaenaisemiseksi. Verkko on valmistettu läpimitaltaan redusoiduista yksisäikeisistä kudoksesta ja kudottu ainutlaatuisella menetelmällä verkoksi, joka on noin 50 prosenttia joustavampi kuin normaali PROLENE™-polypropyleeniverkko. Verkko on kudottu menetelmällä, joka liittyy yhteen jokaisen säikeen haaran, minkä ansiosta se joustaa melkein suuriin. Tämän rakenteen ansiosta verkkoa voidaan leikata minkä tahansa muotoiseksi tai kokoiseksi sen rispaantumatta. Molempisuuntaisen joustavuuden ansiosta verkko sopeutuu moniin erityyppisiin kehon rasituksiin.

Verkkokomplantti

Verkkokomplantti on valmistettu GYNECARE GYNEMESH PS -verkkomateriaalista. Verkkokomplantit on leikattu valmiiksi Y-kojaimen muotoiseksi anterioristen, posterioristen ja/tai apikaalisten emätindefektien korjaamista varten. Katso kuvaa 2. Verkkokomplantissa on kaksi nauhaa ja keskirunko. Verkkokomplantin proksimaalisessa päässä on kärkelelele, josta se voidaan kiinnittää onnellangalla verkon läikkäisen minimioimiseksi nauhojen sijoittamisen aikana. Distaalipäässä on distaaliolvi, mikä helpottaa verkkokomplantin kohdistamista. Verkkokomplantin nauhoissa on taskut sisäänviejiä varten. Verkkokomplantti on valmiina asettimessa, joka koostuu pinnoittamattomasta Tyvek®-materiaalista ja läpinäkyvästä muovikalvosta ja jota verkkokomplantti on helppo ottaa pois.

Anteriorinen sisäänviejä

Anteriorinen sisäänviejä on potilaskohtainen instrumentti, joka on tarkoitettu helpottamaan verkkokomplantin nauhojen sisäänvientiä anteriorisiin dissektoituihin kudoksanaviin. **HUOMAUTUS: Anteriorista sisäänviejiä ei ole tarkoitettu kudoksen dissektointiin.** Anteriorinen sisäänviejä on yhteensopiva verkkokomplantin taskujen kanssa ja sen avulla nauhat voidaan sijoittaa anteriorisesti potilaan kummallekin puolelle. Katso kuvia 3 ja 4.

Posteriorinen sisäänviejä

Posteriorinen sisäänviejä on potilaskohtainen instrumentti, joka on tarkoitettu helpottamaan verkkokomplantin nauhojen sisäänvientiä posteriorisiin dissektoituihin kudoksanaviin. **HUOMAUTUS: Posteriorista sisäänviejiä ei ole tarkoitettu kudoksen dissektointiin.** Vakionallinen neulanallutit kiinnitetään posterioriseen sisäänviejiän sisäänvientiin stabiloinnin hallitsemiseksi. Posteriorinen sisäänviejä on yhteensopiva verkkokomplantin taskujen kanssa ja sen avulla nauhat voidaan sijoittaa posteriorisesti potilaan kummallekin puolelle. Katso kuvaa 5.

Emätintuki

Emätintuki on potilaskohtainen laite, joka on tarkoitettu tukemaan emätinkudoksia kirurgisen verkon asettamisen ja emätinvuonin sulkeamisen jälkeen. Emätintuen kärki on sen levein osa ja sitä voidaan leikata. Kun potilas on mitoitettu, emätintuen kokoa voidaan säätää potilaan koon mukaan leikkauksella määrättyä kärkeä pois. Emätintuki jätetään paikalleen emättimen ylemmän kolmannekseen 3–4 viikon ajaksi ja poistetaan sen jälkeen potilaasta. Katso kuvaa 6.

Pallo

Pallo on potilaskohtainen laite, joka on tarkoitettu korvaamaan leikkauksenjälkeinen emättimen pumpulipaiskumateriaalia. Pallon tilavuutta voidaan säätää emätinkanavan täyttämiseksi ja emätinsienän lähentämiseksi verkkokomplanttien.

22

SUOMI

Pallo toimitetaan valmiiksi emätintukeen kiinnitettynä. Kuvassa 7 esitetään tyhjennetty pallo ilman siihen kiinnitettyä emätintukea. Pallo voidaan jättää paikalleen enintään yhdeksi vuorokaudeksi.

Ruisku

Pallon täyttöä varten pakkauksen mukana toimitetaan 50 ml:n ruisku.

OSA 1: TOIMENPIDEPERIAATTEET GYNECARE PROSIMA -JÄRJESTELMÄÄ KÄYTETÄESSÄ

Lantionpohjan korjaustoimenpiteessä, jossa käytetään GYNECARE PROSIMA -järjestelmää, pyritään korjaamaan lantionlimen laskeuma anatomisesti oikein, pysyvästi ja standardoitua menetelmää käyttäen. Laskeuman sijaintikohdasta ja kirurgin menetelmistä riippuen korjaus voidaan tehdä joko anterioriselta ja/tai posterioriselta puolelta. Kohdunpoisto tai kohdun säilyttäminen voidaan suorittaa samanaikaisesti toimenpiteessä, jossa käytetään GYNECARE PROSIMA -järjestelmää. Jos indikoitu, ponnistussinkontinenssin perineaalinen korjaus tai virtsaputkenlaisen tukinahan asettaminen voidaan suorittaa samanaikaisesti GYNECARE PROSIMA -järjestelmää käytettäessä. Häpytuon taakse tai peittäjälihakseen poikki virtsaputken alapuolelle sijoitettavaa tukinauhaa voidaan käyttää.

Laskeuma korjataan sijoittamalla yksi tai kaksi verkkokomplanttia emättimen kautta. Kirurgisen toimenpiteen jälkeen emätintuki ja täytettyä pallo sijoitetaan emättimeen koon mittamista varten ja emätintuki onnellalla paikalleen, jolloin se tukee emättintä ja verkkokomplanttia kudoksen sisäänkasvuun aikana. Kun pallo on täytetty, se korvaa perinteisen pumpulimateriaalin täyttämällä emätinontelon ja lähentämällä verkkokomplantin emättimeen. Toimenpiteen jälkeisenä päivänä pallo tyhjennetään ja poistetaan emättimestä emätintukea irottamatta. Emätintuki jätetään paikalleen enintään 4 viikoksi toimenpiteen jälkeen, jona aikana kudokas kasvaa sisään verkkokomplanttien.

OSA 2: GYNECARE PROSIMA -JÄRJESTELMÄN MENETELMÄT

Perinteisen kirurgisen lantionlimen laskeuman korjaustoimenpiteen jälkeen korjattu kudokas alituu vatsaontelonsisäiselle paineelle potilaan liikkeessä, yskässä, olennassa ja suoliston tyhjennyksen aikaisen ponnistuksen yhteydessä. Vatsaontelonsisäisen paineen nousut voivat halata paranemisprosessia ja johtaa kirurgisen toimenpiteen epäonnistumiseen ja laskeuman uudelleenesiintymiseen. Vahvistamalla emättimen korjaustoimenpidettä verkkokomplanttia ja tukemalla emättintä emätintuella 3–4 viikon ajan toimenpiteen jälkeen, GYNECARE PROSIMA -järjestelmä vähentää kirurgisen toimenpiteen epäonnistumisen mahdollisuutta ja laskeuman uudelleenesiintymistä.

Anteriorisessa emätinkorjaustoimenpiteessä verkkokomplantin runko sijoitetaan sitä kiristämättä virtsarakon ja emättimen ylemmän kolmanneksen väliin niin, että se ulottuu lateraalisesti lantionkalvon järeneksen tasolle. Posteriorisessa emätinkorjaustoimenpiteessä verkkokomplantin runko sijoitetaan sitä kiristämättä peräsuolen ja emättimen ylemmän kolmanneksen väliin niin, että se sopii lateraalisesti peräsuolen kohottajalihakseen päälle. Verkkokomplantin rungon kärkeen on tarkoitettu ulottua emättimen kärkeen. Anteriorisesti verkkokomplantti voidaan kiinnittää esivesisäiseen kudokseen tai kohdunkaulaan. Posteriorisesti verkkokomplantti voidaan kiinnittää esirektaaliseen kudokseen tai kohdunkaulaan.

Emätintuki tukee emätinkudosta kirurgisen toimenpiteen jälkeen ja edistää emätinkudoksen lähentymistä verkkokomplanttien, kumme kudoksen sisäänkasvuun alkaa. Kudoksen sisäänkasvu verkkokomplantin tapahtuu 3–4 viikon aikana toimenpiteestä. GYNECARE PROSIMA -järjestelmää käytettäessä ei kudosta tarvitse dissektoida lantio-ontelon ulkopuolelta ja eikä onnellanetta ja instrumentteja viedä sisään peittäjälihakseen aukon ja ristiluun-selkäranganiteen kautta, mikä yksinkertaistaa kirurgista toimenpidettä.

Kohdunpoisto

Kirurgi päättää, onko potilaalta poistettava kohtu samanaikaisesti toimenpiteen aikana. Kun kohtu poistetaan, peräsuoli-kohtusvanteen sulkeamista suositellaan, jotta verkkokomplantti ei pääse kosketuksiin suolen kanssa. "T"-vidiosulkeamista on vältettävä, sillä se lisää verkon esiintulon riskiä. Jos kohdunpoisto tehdään samanaikaisesti joko anteriorisen ja/tai posteriorisen korjaustoimenpiteen yhteydessä, kohdunpoiston avausviilto on sijoitettava ensin poikittain ja sitten korjausviilto on tehtävä niin, että ne eivät kosketa toisiinsa suljettua kohdunpoistoviiltoa. Tämä tehdään "T"-viiltoja välttämiseksi.

Kohdun säilyttäminen

GYNECARE PROSIMA -järjestelmä sopii käytettäväksi tilanteissa, joissa kirurgi tai potilas on päättänyt, että kohtua ei poisteta.

Emätinviihlot

Emätinviihlot GYNECARE PROSIMA -järjestelmää käytettäessä ovat samat kuin kirurgien käyttämät avausviilto tavallisissa emättimen korjaustoimenpiteissä. Viiltoit on tehtävä koko emättimen seinämän syvyydeltä verkon suojaamiseksi.

Verkkokomplantin sijoittaminen

Emätintuki pitää verkkokomplantteja paikoillaan kudoksen sisäänkasvuun aikana. Tästä syystä verkkokomplantin nauhoja ei tarvitse kiinnittää paikoilleen. Verkkokomplantin kärkeä voidaan kiinnittää sidekudokasvotuen emättimen käden keskijalalta onnellalle, esim. 2-0 MONOCRYL™ (polylekaproni 25) tai pinnoitettu 2-0 Coated VICRYL™ (polyglaktin 910). Emättimen epiteeliä ei saa onnellalla kiinni verkkokomplanttien.

Emättimen suojaaminen

Liiallista emättimen epiteelin poistamista tai leikkauksia on vältettävä. Kudoksen vaurioitumista voi tapahtua toimenpiteen jälkeen ja heikentynyt emättimen kapasiteetti voi olla haitallista, mikäli tilan paljon emättimen epiteeliä on poistettu.

Emätintuen kolme tasoa

Emätinkorjaustoimenpiteissä on kolme eri tukitasa. GYNECARE PROSIMA -järjestelmä on tarkoitettu käytettäväksi tasojen I ja II tukitoimenpiteisiin seuraavasti:

Taso I – Suspensio ja tuki (emättimen sisempi kolmannes)

Emättimen sisempää kolmannesta (mukaan lukien pohjikka kohdunpoiston jälkeen) ja kohtua tukee kaksi mekanismia. Ensiksi kohtua ja emättimen yläosaa tukevat kohdun vieruskudos (kardinaali- ja ristiluun kohtusiteet) ja emätinenvierereneen kudokas. Näinä kudokset toimivat kannatusteiden tavalla, nousevat periformislihaksen sidekudokasvotusta, suoli-ristiluunvielestä ja lateraalista ristiluusta ja kiinnittyvät emättimen sisempään lateraaliseen kolmannekseen sekä kohdunkaulan posteriori-lateraalille puolelle. Toisaalta kohtua ja emättimen sisempää osaa

tukee epäsuorasti kohottajajäseä, joka muodostuu oikean ja vasemman peräaukon kohottajaliikkeen yhdistymisestä peräsuolen ja häntäluumen välissä. Kohdun ja emättimen laskueuma esiintyy näiden suorien ja epäsuorien tukimekanismien toimintahäiriön seurauksena. Tässä yhteydessä esiintyy todennäköisesti lantionpohjan lihashen ja kehdun vieruskudoksen ja sisempien emättimenvereisten kohottajakudosten heikkoutta. Tason I laskueumadiagnosin tarkoituksena on aikaansaada suora ja epäsuora tukimekanismi. GYNECARE PROSIMA -järjestelmässä käytetään verkkomplantin nauhoja, jotka asetetaan kumpaankin sisempään peittäjälihakseen ja sen päällä sijaitsevaan parietaalikudokseen anteriorisessa emätkinorkjaustoinpenteessä ja ristiluu-selkärankaisteisiin postenorisessa emätkinorkjaustoinpenteessä. Näin emättimen yläosaa ja kohtua kannatetaan suoraan ja epäsuorasti laajalta alueelta verkkomplantin avulla.

Taso II – Lateraalinen kiinnittäminen (emättimen keskiosa)

Lantionkalvon jännekaari kiinnittää emättimen keskiosan lateraalisesti ja suoraan lantion sivuseinämän lihaksiin. Tällä kiinnityksellä anteriorinen ja posteriorinen emättimen seinämä venytetään oikean ja vasemman lateraalisen kiinnityskohdan välillä. Tason II laskueuman korjauksella pyritään kiinnittämään lateraalinen emättimen keskikohta uudelleen lantion sivuseinämän lihaksiin. Emättimen keskikohdan defektit vaativat myös tason II tukea. Kun toimenpiteessä käytetään GYNECARE PROSIMA -järjestelmää, emätkin kiinnitetään uudestaan lantion sivuseinämän lihaksiin ja sidekalvo tukee myös keskiosaa kudoksen sisäänkasvun jälkeen.

Taso III – Fuusio (emättimen ulompi osa)

HUOMAUTUS: Tätä aluetta ei tarvitse dissektoida GYNECARE PROSIMA -järjestelmää käytettäessä.

Tasolla III emättimen ulompi osa yhdistyy anteriorisella puolella perineaalikalvon ja virtsaputken kanssa. Posteriorisella puolella emättimen alaosaa yhdistyy perineaalikudoksen ja peräaukon kohottajaliikkeen kanssa. Kudokset korjataan tällä alueella ilman verkkomplanttia, sillä sitä ei ole tarkoitettu käytettäväksi emättimen ulomassa osassa. GYNECARE PROSIMA -järjestelmällä ei hoideta tason III tukidefektejä, vaikka ne voidaan käsitellä samankaltaisesti esim. perineorrafialla.

OSA 3: KÄYTTÖOHJEET

HUOMAUTUS: Tämän asiakirjan alussa olevia kuvia on seurattava tätä osaa luettaessa.

Kirurgiseen toimenpiteeseen valmistelu

GYNECARE PROSIMA -järjestelmää käytettäessä toimenpide voidaan suorittaa yleis- tai paikallispudotuksessa kirurgin, nukutuslääkärin ja potilaan toiveiden mukaisesti.

Potilas on asetettava selinmakualle pakarat jonkin verran teikkaukspöydän ulkopuolella ja lonkat koukistettuna. Virtsarakko voidaan tyhjentää kirurgin harkinnan mukaisesti. Katetri tarvitaan ennen palon täyttämistä ja se voidaan asettaa paikalleen tässä toimenpiteen vaiheessa.

GYNECARE PROSIMA -järjestelmän käyttö kohdunpoiston jälkeisissä toimenpiteissä

Anteriorinen emätkinorkjaustoinpide

Kun ainoastaan anteriorisen emättinseinämän vahvistusta tarvitaan, ainoastaan anteriorista lantionpohjan GYNECARE PROSIMA -korjausjärjestelmää tulisi käyttää. Tähän kuuluu yksi verkkomplanti ja erityisesti tarkoitusta varten suunniteltu anteriorinen sisäänviejä, jota käytetään anteriorisessa emätkinorkjaustoinpenteessä. Kun tarvittavat emätinviillot ja dissektiot on tehty, aikaansaadaan kudoksanavat anteriorisella puolella verkkomplantin nauhojen sijoittamiseksi anteriorista sisäänviejää käyttäen. **HUOMAUTUS: Anteriorista sisäänviejää ei saa käyttää kudoksen dissektointiin.**

Anteriorinen emätin dissektio

Anteriorinen emätinpeite irrotetaan virtsarakosta. Dissektio emättimen seinämää koko paksuudeltaan. Tämä dissektio pitäisi suorittaa epiteelikalaisena hydrodissektiona. Emättimen seinämän pinnan dissektiota tai emättimen seinämän erottamista kahdeksi kerrokseksi on vältettävä. Tämä voi johtaa hyvin ohueen emättimen seinämään ja häiritä emättimen seinämän verenkiertoa ja lisätä verkkomplantin esiintuloa. Jos dissektiota lateraalisesti lantion sivuseinämää ja istuinluun kärkeä kohti.

Anteriorisen kanavan dissektio ja verkkomplantin sijoittaminen

Tässä kuvataan dissektiota, jossa luot kanavat verkkomplantin nauhoille ensin potilaan oikealle puolelle ja sen jälkeen vasemmalle puolelle. Nämä kanavat aikaansaadaan siitä syystä, että verkkomplanti voidaan sijoittaa niin, että nauhojen distaaliosat ovat tasan lantion sivuseinämää ja sisemmän peittäjäliikkeen parietaaliskaa vasten. Näiden nauhojen sijoittamisessa alota dissektio pöydäpuolelta ja tunnistamalla istuinluun kärki potilaan kummaltakin puolelta. **HUOMAUTUS: Tämä dissektio voidaan vaihtoehtoisesti alustaa saksilla käyttäen "työntö-levitysmenetelmää", jossa saksien kärjet pysyvät koko ajan istuinluun kärkeä vasten.** Dissektio kudos alku-dissektion jälkeen arvoasti sormin istuinluun kärkeen asti. Kun kontakti istuinluun kärkeen on saavutettu, etusormella aikaansaadaan tila anterioriselle puolelle istuinluun kärkeä yläpuolelle. Katso kuvaa 8A. Tämän dissektion suunta on suorassa kulmassa lantion sivuseinämää ja aikaansaada noin 2 cm leveä ja 3 cm korkea tila. Anteriorisessa dissektiossa ei dissektoida ristiluu-selkärankaiteita. Tämän dissektiota aikaansaada kanavan istuinluun yläpuolelle anteriorisella puolella ja lantionkalvon jännekaaren, sisemmän peittäjäliikkeen ja sen seinämäsidekuduskalvon yläpuolelle. Suorita sama dissektio potilaan vasemmalle puolelle.

Esiheikkalasta kudosta ei tarvitse poimuttaa. Jos se poimutetaan, ainoastaan kudoksen keskiosa poimutetaan. Tällä estetään dissektion alueen tekeminen liian kapeaksi. Sijoita verkkomplanti esiheikkalaisen kudoksen päälle niin, että nauhojen taskut osoittavat ylöspäin. Jos verkko kiinnitetään, se on tehtävä tässä vaiheessa toimenpiteitä sijoittamalla ommei, esim. 2-0 MONOCRYL tai pinnoitettu 2-0 Coated VICRYL, emättimen kärkeen ja pujottamalla ommei verkkomplantin kärkielekkeen läpi. Ommei voidaan solmia kiinni tässä vaiheessa tai nauhojen sijoittamisen aikana. Verkkomplantin distaalioven kiinnittäminen on valinnainen ja se voidaan suorittaa esim. 2-0 MONOCRYL -tai pinnoitetulla 2-0 Coated VICRYL -ommalineilla.

Sijoita verkkomplantin nauhat anteriorista sisäänviejää käyttäen anteriorisen dissektion aikaansaamiin oikean- ja vasemmanpuoleisiin kanaviin istuinluun yläpuolella (edellä kuvattu mukaisesti). **HUOMAUTUS: Anteriorisen sisäänviejän kaarevat päät kääntyvät vastakkaisiin suuntiin ja kummassakin päässä on sijoitusuuntana osoittavat nuolet.** Nuolen osoittaessa potilaan oikealle puolelle anteriorisen sisäänviejän kärki yönnetään verkkomplantin taskuun (kuva 8B) potilaan oikealla puolella. **HUOMAUTUS: Kiristämisen voi auttaa pitämään anteriorisen sisäänviejän taskussa.** Pidä anteriorista sisäänviejää pystyasennossa niin, että instrumentin kaareva osa on emättimen posteriorista sisäänviejää vasten. Työnnä anteriorista sisäänviejää (nauha ladattuna) nyt aiemmin aikaansaatuun kudoksanavaan (kuva 8C, kunnex kahva koskettaa joja häpyhuolia vastakkaisella puolella. Tämä aikaansaadaan sijoittamalla anteriorisen sisäänviejän kahvaosa ylöspäin ja pystysuuntaan niin, että etureuna ja tasku osoittavat istuinluun kärkeä kohti. Kun sisäänviejä on sijoitettu, siirrä kahvaa alas niin miltei vaakasuuntaiseen asentoon samalla, kun kahvan kontakti vastakkaisen puolen reiden kanssa ylläpidetään. **HUOMAUTUS: Virtsarakon sivun työntämisen kirurgisella vakioinstrumentilla voi auttaa sisäänviejän ohjaamista kanavaan.** Haluttaessa etusormea voidaan käyttää ohjainena kanavassa ohjaamaan anteriorinen sisäänviejä isoihin häpyhuoliin vastakkaisella puolella ennen kahvan laskemista. Sisäänviejän varovainen työntäminen ylöspäin varmistaa, että nauhojen taskut ovat oikeilla paikoillaan ja verkkomplantin kärkiosa on emättimen kärkeä vasten. **HUOMAUTUS: Jos nauhojen sisäänviennin aikana tuntuu vastusta, määritä vastuksen syy ennen toimenpiteen**

jatkamista. Sisäänviejän työntäminen eteenpäin tässä tapauksessa voi johtaa verkkomplantin vaurioon tai sen työntämisen liian pitkälle, mikä voi vaurioittaa kriittisiä kudorakenteita.

Anteriorinen sisäänviejä poistetaan nostamalla kahva takaisin pystyasentoon. Ennen poisvetämistä ja jättämällä nauha kanavaan. **HUOMAUTUS: Vie ensimmäinen nauha kokonaan sisään. HUOMAUTUS: Jos anteriorinen sisäänviejä vedetään pois ennen kuin verkkomplantin nauha on kohteessa, nauha on poistettava, ladattava uudestaan ja vietävä uudestaan sisään.** Suorita toimenpide potilaan vastakkaisella puolella kääntämällä anteriorinen sisäänviejä toisinpäin ja viemällä pää, joka osoittaa potilaan vasenta puolta kohti toiseen taskuun. Kuvassa 8D esitetään molemmat nauhat paikalleen sijoitetuina. **HUOMAUTUS: Toisen nauhan sijoittamisen aikana on varottava liikuttamasta verkkomplanttia ja varmistettava, että verkkomplanti ei ole vääräntynyt.**

Sijoita verkkomplantin runko löysälle alla olevan emätinkudoksen päälle. Rungon ja nauhojen taittamista tai väntämistä on vältettävä. Verkkomplantin runkoa voidaan joutua leikkaamaan emättimen kuoista tai lateraalista dissektoinnista riippuen. Emätinpeiteellä voidaan leikata, mutta liiallista emätinpeiteelin poistamista on vältettävä. Sulje epiteidi verkkomplantin päälle ilman liittäisiä ompeluita (kuvataan alla, kuva 8E). Verkkomplantin lopullinen sijainti anteriorisella puolella esitetään kuvassa 8F.

HUOMAUTUS: Varmista, että hemostaasi on saavutettu ennen emätinviillon sulkemista ja sen sulkemisen jälkeen.

Sulje emätinviillot ilman liittäisiä tai kahdeksikko-ompeluita. Tämä estää emätinpeiteelin devaskularisaatiota viitokudossa ja vähentää verkon eroosiota. Suosittelemme epiteelin sulkemista kahdessa kerroksessa suhteellisen vahvan ommeinin aikaansaamiseksi emätinviillossa. Sulje alempi kerros jatkuuilla epiteelikalaisilla ei-limittäisillä ompelilla käyttäen esim. 2-0 MONOCRYL -tai antibakteerista MONOCRYL Plus™ -ommalineetta (poliglekaproni 25). Sulje epiteeli sitten ei-limittäisillä jatkuuilla pinto-ompelilla käyttäen esim. pinnoitettua 2-0 Coated VICRYL -tai pinnoitettua antibakteerista Coated VICRYL Plus™ -ommalineetta (polyglaktin 910). **HUOMAUTUS: Verkkomplanti sijoitetaan emättimen yläosaan, eikä verkkomplanttia saa leikata sisemmän kolmannuksen alapuolelta.** Jos kystoskopiaa ei ole vielä suoritettu, suosittelemme sitä virtsateiden vaurioiden poissulkemiseksi.

Vaihtoehtoisesti emättimen seinämää voidaan sulkea yhtenä kerroksena. Sulku toimenpiteessä voidaan käyttää ei-limittäisiä pinto-ompeluita tai yksittäisiä ompeluita esim. pinnoitettua 2-0 Coated VICRYL -tai pinnoitettua 2-0 Coated VICRYL Plus -ommalineetta.

Posteriorinen emättimen korjaustoinpide

Kun ainoastaan posteriorisen emättinseinämän vahvistusta tarvitaan, käytä ainoastaan posteriorista lantionpohjan GYNECARE PROSIMA -korjausjärjestelmää. Siihen kuuluu yksi verkkomplanti ja erityisesti posterioriseen emätkinorkjaustoinpenteeseen tarkoitettu posteriorinen sisäänviejä. Kun tarvittavat emätinviillot ja dissektiot on tehty, aikaansaadaan kudoksanavat posteriorisella puolella verkkomplantin nauhojen sijoittamiseksi posteriorista sisäänviejää käyttäen. **HUOMAUTUS: Posteriorista sisäänviejää ei saa käyttää kudoksen dissektointiin.**

Posteriorinen emättimen ja kanavan dissektio

Irrota posteriorinen emätinpeiteeli peräsuolen etuosan kudoksesta. Kuten anteriorisen emättimen seinämän kohdalla, posteriorinen emättimen seinämä dissektoidaan sen koko paksuudelta. Tämä dissektio pitäisi suorittaa epiteelikalaisena hydrodissektiona. Jos dissektiota lateraalisesti kummaltakin puolelta peräsuolen kohottajaliikkeen istuinluun kärkeä tasolla. Jos dissektiota kumminkin kohottajaliikkeen läpi ristiluu-selkärankaisteeseen, mutta ei niiden läpi, aikaansaadaan kanavat, joihin verkkomplantin nauhat sijoitetaan. Katso kuvaa 9A.

Potilaalla esiintyvä enteroseleen hallinta on valinnainen, mutta jos se suoritetaan, se voidaan suorittaa tässä vaiheessa toimenpiteitä kirurgin harkinnan mukaisesti.

Jos peritoneaalinen ontelo on avattu joko anteriorisen tai posteriorisen dissektion aikana, se on suljettava ennen verkon kiinnittämistä.

Posteriorisen verkkomplantin sijoittaminen

Peräsuolen etupuolelta kudosta ei tarvitse poimuttaa. Jos peräsuolen etupuolinen kudok poimutetaan, ainoastaan peräsuolen etupuolisen kudoksen keskiosa poimutetaan. Tällä estetään dissektion alueen tekeminen liian kapeaksi. Sijoita verkkomplanti peräsuolen etupuolisen kudoksen päälle niin, että nauhojen taskut osoittavat ylöspäin. Jos verkko kiinnitetään, se on tehtävä tässä vaiheessa toimenpiteitä sijoittamalla ommei, esim. 2-0 MONOCRYL tai pinnoitettu 2-0 Coated VICRYL, emättimen kärkeen ja pujottamalla ommei verkkomplantin kärkielekkeen läpi. Ommei voidaan solmia kiinni tässä vaiheessa tai nauhojen sijoittamisen aikana. Verkkomplantin distaalioven kiinnittäminen on valinnainen ja se voidaan suorittaa esim. 2-0 MONOCRYL -tai pinnoitetulla 2-0 Coated VICRYL -ommalineilla.

Sijoita verkkomplantin nauhat posteriorista sisäänviejää käyttäen dissektion aikaansaamiin oikean- ja vasemmanpuoleisiin kanaviin kumpaankin ristiluu-selkärankaisteita kohti (edellä kuvattu mukaisesti). Tartu posterioriseen sisäänviejään suoralla neulankuljettimella kuvan 9B mukaisesti. **HUOMAUTUS: Aseta neulankuljettimen kärki posteriorisen sisäänviejän suoraan laveliseen päähän.** Varmista, että kiinnitetty posteriorinen sisäänviejä on samassa linjassa neulankuljettimen kahvan kanssa. Työnnä posteriorisen sisäänviejän kärki potilaan oikealla puolella olevaan hihnatakuun (kuva 9B). Ohjaa posteriorinen sisäänviejä nyt nauha ladattuna aiemmin aikaansaatuun kudoksanavaan (kuva 9C) neulankuljettimen kahvan ollessa pystyasennossa. Aseta nauha koko pituudeltaan kanavaan niin, että nauhan alaosaa koskettaa sidekudosdissektion yläosaa. **HUOMAUTUS: Vie ensimmäinen nauha kokonaan sisään. Jos sisäänviejä vedetään pois ennen kuin nauha on kohteessa, nauha on poistettava, ladattava uudestaan ja vietävä uudestaan sisään. HUOMAUTUS: Nauhaa ei saa viedä liian syvälle kriittisten kudorakenteiden vaurioiden estämiseksi. HUOMAUTUS: Jos nauhojen sisäänviennin aikana tuntuu vastusta, määritä vastuksen syy ennen toimenpiteen jatkamista. Sisäänviejän työntäminen eteenpäin tässä tapauksessa voi johtaa verkkomplantin vaurioon tai sen työntämisen liian pitkälle, mikä voi vaurioittaa kriittisiä kudorakenteita.** Vedä posteriorinen sisäänviejä pois sisäänvientiä pitkin ja nauha jätetään kanavaan. Nauhat koskettavat ristiluu-selkärankaiteita, mutta eivät penetroi niitä. Älä sijoita ompeluita ristiluu-selkärankaisteisiin. Toinen nauha sijoitetaan potilaan vasemmalle puolelle toistamalla toimenpide. Kuvassa 9D esitetään molemmat nauhat paikalleen sijoitetuina. **HUOMAUTUS: Toisen nauhan sijoittamisen aikana on varottava liikuttamasta verkkomplanttia ja varmistettava, että verkkomplanti ei ole vääräntynyt.**

Sijoita verkkomplantin runko löysälle alla olevan emätinkudoksen päälle. Vältä verkkomplantin rungon ja nauhojen taittamista tai väntämistä. Verkkomplantin runkoa voidaan joutua leikkaamaan emättimen kuoista tai lateraalista dissektoinnista riippuen. Posteriorisen seinämän emätinpeiteellä voidaan leikata, mutta liiallista emätinpeiteelin poistamista on vältettävä. Sulje posteriorisen emättinseinämän epiteeli verkkomplantin päälle ilman liittäisiä ompeluita (kuvataan alla). Verkkomplantin lopullinen sijainti sijoitettuna puolella esitetään kuvassa 9E.

HUOMAUTUS: Varmista, että hemostaasi on saavutettu ennen emätinviillon sulkemista ja sen sulkemisen jälkeen.

Sulje emätinviilut ilman liittimiä tai kahdeksikko-ompeleita. Tämä estää emätinpiteelin deskuularisaatiota välttökohtassa ja vähentää verkon eroosiota. Suosittelemme epiteelin sulkemista kahdessa kerroksessa suhteellisen vahvan ommelviin aikaansaamiseksi emätinviilessä. Sulje alempi kerros jatkuvilla epiteelinauhoilla ei liimitäällä ompeleilla käyttäen esim. 2-0 MONOCRYL tai tällöin teenistä 2-0 MONOCRYL Plus -ommelainetta. Sulje epiteeli sitten ei liimitäällä jatkuvilla pisto-ompeleilla käyttäen esim. pinnoitettua 2-0 Coated VICRYL tai pinnoitettua 2-0 Coated VICRYL Plus -ommelainetta. **HUOMAUTUS: Verkkoinplantti sijoitetaan emättimen sisempään osaan, eikä verkkoinplanttia saa leikata sisemmän kolmanneksen alapuolelta.** Toimenpiteen jälkeen on suoritettava tuseeraus rektaalivaurioiden poissulkemiseksi.

Vahtoitohtoisesti emättimen seinästä voidaan sulkea yhtenä kerroksena. Sulkutoimenpiteessä voidaan käyttää ei-liittimiä pisto-ompeleita tai yksittäisiä ompeleita esim. pinnoitettua 2-0 Coated VICRYL tai pinnoitettua 2-0 Coated VICRYL Plus -ommelainetta.

Yhdistetty anteriorinen ja posteriorinen emättimen korjaustoimenpide

Kun emättimen seinämää on tuettava sekä anterioriselta että posterioriselta puolelta, käytetään yhdistettyä lantionpohjan GYNECARE PROSIMA -korjausjärjestelmää. Tähän kuuluu kaksi identtistä verkkoinplanttia, yksi anteriorista korjausta ja toinen posteriorista korjausta varten. Käytä ainoastaan kaarevaa anteriorista sisäänvievää anteriorisen puolen korjaukseen ja ainoastaan suoraa posteriorista sisäänvievää posterioriseen korjaukseen. Suorita anteriorinen ja posteriorinen emättimen korjaustoimenpide yllä kuvatulla tavalla. Suosittelemme, että anteriorinen toimenpide suoritetaan ensin. Verkkoinplanttien lopullinen sijainti anteriorisella ja posteriorisella puolella esitetään kuvassa 10. Kun toimenpide on suoritettu, kystoskopiaa suositellaan virtsatie vaurioiden poissulkemiseksi. Tuseeraus on suoritettava rektaalivaurioiden poissulkemiseksi.

GYNECARE PROSIMA -järjestelmän käyttö, kun kohtua ei poisteta (kohdun ripustus)

Jos laskeuman sisältävä kohtua ei poisteta, verkkoinplantin kärkelele kiinnitetään kohdunkaulaan. Verkkoinplantti kiinnitetään kohdunkaulaan häpyluu-kohdunkaulan renkaan tasolla anteriorisen tai posteriorisen emättimen korjaustoimenpiteen aikana.

Kun kohtua ei poisteta anteriorisen emätinkorjaustoimenpiteen aikana, häpyluu-kohdunkaulan rengas otetaan ensin anteriorisen disektion aikana. Sijoita 2-0 PROLENE -ommett tekevästi kiinni häpyluu-kohdunkaulan renkaan anterioriselle puolelle. Sama ommit kiinnitetään verkkoinplantin kärkelelekin läpi. Kiekkoon PROLENE -ommit soidaan sen jälkeen, kun verkkoinplantin nauhat ovat paikoillaan. Tämä kiinnittää verkkoinplantin kohdunkaulan anterioriselle pinnalle häpyluu-kohdunkaulan renkaan tasolla ja varmistaa, että verkkoinplantti lasjenee emättimen kanssa, kun emätintuki on sijoitettu asianmukaisesti.

Kiinnitä posteriorisessa korjaustoimenpiteessä verkkoinplantti posterioriseen kohdunkaulaan häpyluu-kohdunkaulan renkaan tasolle tai yläpuolelle. Peräsuoli-kohtausväne voidaan avata, kun verkkoinplanttia kiinnitetään kohdunkaulaan. Sulje vatsakalvo tämän ompeleen yläpuolelta sen estämiseksi, että suoli ei kiinnity verkkoinplanttiin. Jos kirurgi päättää olla avaamatta peräsuoli-kohtausvänettä, häpyluu-kohdunkaulan rengas tulee ensin posterioriseen emätinrikkoon aikana. 2-0 PROLENE -ommit sijoitetaan tekevästi kiinni häpyluu-kohdunkaulan renkaan posterioriselle puolelle. Sama ommit kiinnitetään verkkoinplantin kärkelelekin läpi. PROLENE -ommit soidaan sen jälkeen, kun verkkoinplantin nauhat ovat paikoillaan. Tämä kiinnittää verkkoinplantin kohdunkaulan posterioriselle pinnalle häpyluu-kohdunkaulan renkaan tasolla.

Kun verkkoinplantteja käytetään sekä anterioriseen että posterioriseen emätinkorjaustoimenpiteeseen, ne on kiinnitettävä kohdunkaulan anterioriselle ja posterioriselle puolelle yllä kuvatun mukaisesti (kuva 11).

Verkkoinplantin hygieniä

Huuhtele emätinviiluja kirurgisen toimenpiteen aikana keittosuolaliuoksella. Minimoi verkkoinplantin käsittely ja huolehdi asianmukaisesta hygieniasta.

Emättimen ja pallon sijoittaminen

Kun toimenpide on suoritettu, sijoita emättimeen oikeankokoinen emätintuki ja pallo, ja ompele ne paikalleen irtoamisen estämiseksi. Emättimesta on saatavana kolme eri kokoa (pieni, keskikokoinen ja suuri) ja kirurgi voi räätälöidä sen potilaan emättimen pituuden mukaan seuraavasti.

Emättimen sovittaminen ja leikkaaminen

Emätintuki toimitetaan suurimmassa mahdollisessa kokossa. Potilaalle sopivankokoinen emätintuki mitataan käyttämällä emätintukea itseään koon arvioitain. Suurkokoinen emätintuki sijoitetaan emättimen laajennetun kärjen ja emättimen ulkoaukon väliin. Emätintuki viedään emättimeen tarttumalla sen leveimpään kohtaan ja täyttämällä se pituussuuntaan niin, että pallo osuuttaa ylöspäin (kuva 12). Emättimen levein osa viedään sisään ensin niin, että ommeleirät sijoittuvat juuri emättimen ulkoaukon yläpuolelle. **HUOMAUTUS: Palloa ei saa irrottaa tai vauriuttaa emättimen kuon mittauksen aikana.** Emätintuki on oikeankokoinen, kun se sopii kunnolla laajennetun emättimen sisempään kolmanneksen niin, että distaalipää ja ommeleirät ovat 1 cm emättimen ulkoaukon yläpuolella (kuva 13).

Jos suuri koko sopii, emätintukea ei tarvitse leikata. Jos potilaalle käytetään keskikokoa, yläosa poistetaan varovasti leikkamalla käyttäen ainoastaan kaarevia Mayo-saksen kirkkiä ja leikkamalla yläosa pienellä osaa varmistuen samalla, että leikkauksena on tasainen. Leikkaukselle jäävän materiaalin määrä on minimoitava huolellisesti. **HUOMAUTUS: Emätintuki on määriteltävä erittäin huolellisesti. Kun emätintuki on leikattu, sitä ei voi palauttaa suuremman kokoiseksi eikä leikattuja osia kiinnitä uudelleen.** Siinä pallo pois tieltä leikkaamisen ajaksi (kuva 14). **Pallon on varottava vaurioittamasta emättimen leikkauksen aikana.**

Jos keskikoko on sopiva, emätintukea ei tarvitse leikata enempää. Jos pientä kokoa halutaan käyttää, jäljellä oleva leikattava osa poistetaan yllä annettujen ohjeiden mukaisesti. Siirrä pallo pois tieltä leikkaamisen ajaksi sen vaurioittamisen estämiseksi.

Kun emätintuki on mitoitettu oikein ja pallo sijoitettu takaisin paikalleen, kokoonpano voidaan viedä sisään potilaan emättimeen. **HUOMAUTUS: Pallon perforoinnin minimoimiseksi nitään instrumentteja ei saa käyttää apuna avustamaan emättimen tai pallon sisäänvientiä.** Jos pallo vaurioituu, posta se emättimesta ja käytä pumpulimateriaalia emätintuen sijoittamiseen.

Kun kokoonpano on sijoitettu asianmukaisesti potilaan laajennetun emättimen sisempään kolmanneksen, kiinnitä emätintuki paikalleen yhdellä ompeleella kummankin ommeleirän läpi posterioriseen emättimen seinämän epiteeliin, lateraalisesti ja emättimen ulkoaukon yläpuolelle molemmille puolille kuvan 15 mukaisesti klo 4.00:n ja 8.00:n kohdalle. Sido oikean- ja vasemmangpuoleiset ommeleet vuoroaen pitäen emätintukea tekevästi paikallaan emättimessä. **HUOMAUTUS: Palloa ei saa puhkaista, kun emätintukea ommellaan kiinni paikalleen.** Kiinnittämiseen suositellaan pinnoitettua 2-0 Coated VICRYL -ommelainetta tai vastaavaa resorboituvaa ommelainetta.

Pallon täyttämisen

Kun emätintuki on ommeltu paikalleen, lukitse pakkauksen mukana toimitettu 50 ml:n ruisku pallon venttiiliin kääntämällä. **HUOMAUTUS: Pallon perforoinnin vähentämiseksi emätintuen sijoittamisen jälkeen.** Täytä ruiskua ensin pienellä määrällä huuonilmaa (kuva 16) ja palpoi sitten palloa koko mitallaan sormella sen varmistamiseksi, että pallo on aktivoitunut ja sijaitsee emättimessä koko emättimen pituudelta. Kun aktivoitui on varmistettu, poista sormi ja jatka pallon täyttämistä, kunnes ainoastaan sormenpää sopii kunnolla emättimen ulkoaukon pallon ja emättimen seinämän välissä. Emätintukea on stabiloitava palloa täytettäessä. Täytetty pallo kiinnittää verkkoinplantin emättimen seinämään. Pallon täyttöön vaadittava ilmamäärä riippuu potilaasta. **HUOMAUTUS: Pallon enimmäistäyttötilavuus on 90 ml.** Kun pallo on riittävän täysi, irrota ruisku venttiilistä sitä kääntämällä.

Pallon täyttöetkun on tultava ulos emättimestä ja se on kiinnitettävä potilaan reiteen. Korkki on kiinnitettävä pallon venttiiliin ja varmistettava, että pallossa ylläpidetään määritettyä ilmailevuutta (kuva 7). **HUOMAUTUS: Älä kiskä korkkia liika.** Tarvittaessa palloa voidaan säätää myöhemmin käyttäen vakioallista ruiskua pallon sisällä olevan ihmäärään lisäämiseksi tai vähentämiseksi. Palloa voidaan palpoida nilloin tahansa tai varmistaa visuaalisesti, että siinä on riittävästi ilmaa. **HUOMAUTUS: Kun potilas liikkuu, pallo asetuttu emätintontelon ja voi näyttää, että sen paine nousee tai laskee. Tämä on normaalia.**

HUOMAUTUS: Palloa ei saa irrottaa emättimesta ennen käyttöä.

HUOMAUTUS: Palloa ei saa täyttää ennen sen sisäänvientiä emättimeen.

HUOMAUTUS: Jos pallon täyttämisen jälkeen emättimen ommelreiat ovat siirtyneet yli 1 cm emättimen ulkoaukon yläpuolelle tai jos ommeleirät ovat liian kireällä, pallon painetta on laskettava ja emätintuki tarvittaessa sijoitettava tai mitoitettava uudelleen.

HUOMAUTUS: Jos pallossa näkyy reikiä tai jos vuoto on havaittu tai pallo ei pysy täytettynä sen täyttämisen jälkeen, pallo EI SAA käytä. Pallo on poistettava emättimesta ja hävitettävä asianmukaisesti. Käytä vakioallista pumpulipakkauksmateriaalia pallon sijasta.

HUOMAUTUS: Jos pallon liitin irtoaa emättimesta, se on työnnettävä takaisin paikalleen.

HUOMAUTUS: Pallon täyttölukua ei saa kiinnittää emättimeen.

HUOMAUTUS: Vaurioiden estämiseksi täyttölukua ei saa täyttävä liika, kirstiä tai viäntää.

HUOMAUTUS: Pallon kanssa ei saa käyttää pumpulimateriaalia.

Pallon poistaminen emättimesta

Tyhjennä pallo kokonaan ja poista se potilaasta vakioallista ruiskua käyttäen vuorokauden kuluutta. Jätä emätintuki paikalleen. **HUOMAUTUS: Palloa ei saa jättää emättimeen vuorokautta pidemmäksi ajaksi.**

1) Irrota pallon venttiilin korkki.

2) Kiinnitä vakioallinen 50 ml:n (tai suurempi) ruisku pallon venttiiliin ja tyhjennä pallo kokonaan (kuva 17). On tärkeää, että pallo tyhjenetään kokonaan ennen kuin sitä yritetään poistaa emättimesta. **HUOMAUTUS: Kokonaan tyhjennetty pallo aiheuttaa sen, että ruiskun mäntä vetäytyy sisään ilman poistamisen jälkeen.**

3) Poista ruisku.

4) Pallo voidaan nyt irrottaa emättimesta poistaa potilaasta vetämällä sitä varovasti kaudaalseen suuntaan täyttölukusta pallon liittimen läheiltä ja pitämällä samalla varovasti sormella kiinni emättimen distaalipäästä. Katso kuvaa 18.

HUOMAUTUS: Palloa ei saa vetää pois, ellei se ole kokonaan tyhjä eikä vastusta tunnu. Jos vastusta tuntuu, määrää vastuksen syy ennen toimenpiteen jatkamista. Pallon sisäänviennin tai poisvettämisen jatkaminen vastusta tunnettaessa voi johtaa emättimen liikkumiseen ja/tai emättintontelon kudosvaurioon. Täydellinen pallon tyhjentymisen varmistetaan kiinnittämällä ruisku uudestaan ja poistamalla kaikki ilma ennen pallon poistamista.

Emättimen poistaminen potilaasta

Poista emätintuki potilaasta sen jälkeen, kun parantuminen on riittävä, noin 3–4 viikon kuluttua toimenpiteestä. Tähän mennessä resorboituvat ommeleet ovat mahdollisesti sulaneet tai menettäneet riittävästi vetovojuuttaan ja emätintuki voidaan poistaa helposti ilman ompeleiden aiheuttamaa vastusta. **HUOMAUTUS: Poistamistoimenpiteessä voidaan joutua leikkaamaan molemmat ommeleet. HUOMAUTUS: Emätintukea ei saa jättää emättimeen 4 viikkoa pidemmäksi ajaksi.** Poista kaikki emättimen kiinnitysompeleet. Irrota emätintuki manuaalisesti emätinkannavasta kuvan 19 mukaisesti.

Perioperatiivinen hoito

Profylaktista antibioottilääkitystä voidaan antaa kirurgin normaalin käytännön mukaisesti. Antibioottihoidoa voidaan jatkaa toimenpiteen jälkeen kirurgin harkinnan mukaan. Profylaktista tromboembolista hoitoa voidaan antaa.

Kirurgin on kerrottava potilaalle, että emättimeen leikkauksen jälkeen neljäksi viikoksi jätettävän emättimen tarkoitus on tukea emätintä verkkoo vasten paranemisprosessin aikana. Potilaalle on kerrottava, että emätintuki poistetaan leikkauksen jälkeisen seurantakäynnin aikana, noin 4 viikkoa leikkauksen jälkeen. Potilaalle on kerrottava, että leikkauksen jälkeen voi esiintyä emätinvuotaa ja että emätintuki voi liikkua jonkin verran alaspäin. Jos potilas tuntee, että emätintuki on liikkunut alaspäin, hän voi työntää sitä varovasti ylöspäin mukavampaan asentoon. Jos emätintuki aiheuttaa huomattavaa epänykävyyttä, potilaasta on pyydetävä ottamaan yhteyttä lääkäriin.

Kun potilas kotiutetaan sairaalasta, häntä on neuvottava pidättäytymään vaativasta rasituksesta 3–4 viikon ajan. Tänä aikana lantioikudus kasvaa sisään verkkoinplanttiin ja potilas voi alkaa normaali päivärutiini. Potilaasta on neuvottava välttämään yhdystää vähintään 6 viikon ajan leikkauksen jälkeen. Lantionpohjan voimistusta voidaan suositella välittömästi leikkauksen jälkeen.

SUORITUSKYKY

Elämällä suoritettui kokeet osoittavat, että GYNECARE GYNEMESH PS -verkon asettaminen aiheuttaa minimaalisen tai vähäisen tulehdusreaktion, joka on tilapäistä ja jonka jälkeen ohut, kultainen kudoskerros kiinnittyy verkkoon ja voi kasvaa verkon rakojen läpi, mikä yhdistää verkon viereiseen kudokseen. Verko säilyi pehmeänä ja joustavana, eikä se häiritse näkyvästi normaalia haavan paranemisprosessia. Materiaali ei resorboidu, eikä se myöskään hajoa tai heikene kudosentymien vaikutuksesta.

KONTRAINDIKAATIOT

- Kun GYNECARE GYNEMESH PS -verkkoa käytetään vastasyntyneillä, lapsilla, raskaana olevilla naisilla tai raskautta suunnittelevilla naisilla, kirurgin on otettava huomioon, ettei verkko veny merkittävästi potiaan kasvessa.
- GYNECARE PROSIMA -järjestelmää ei saa käyttää raskaana olevilla naisilla tai potilailla, joilla esiintyy infektiota tai emättimen, kohdunkaulan tai kohdun syöpää.

VAROITUKSIA JA VAROITAMIA

- Käyttäjän on tunnettava lantionpohjan korjauksia ja resorbioitumattomia verkkoja koskevat toimenpiteet ja menetelmät ennen lantionpohjan GYNECARE PROSIMA -järjestelmien käyttöä.
- GYNECARE PROSIMA -järjestelmän käyttöä ei ole arvioitu täysin potilailla, joilla on vaiheen IV lantionlehten laskeuma. Tästä syystä sen käyttöä näillä potilailla ei suositella.
- Hyväksyttyjä leikkauksimenetelmiä on noudatettava GYNECARE PROSIMA -toimenpiteessä ja tulehtuneiden tai kontaminoituneiden haavojen hoidossa.
- GYNECARE PROSIMA -järjestelmää ei saa käyttää, jos kirurgisen toimenpidealueen epäillään olevan tulehtunut tai kontaminoitunut. Jos verkkoinplanttia tai emätintuki-pallokokoonpanon käytetään kontaminoituneilla alueilla, on otettava huomioon että myöhempi infektio voi vaatia sen poistamista.

- Leikkauksen jälkeen potilasta on neuvottava pidättäytymään raskaiden esineiden nostamisesta ja/tai liikkunnasta (esim. pyöräily, hiihtäminen) 3–4 viikon ajan, sekä pidättäytymään yhdynnästä 6 viikon ajan, tai kunnes lääkäri päättää milloin potilas voi palata normaaleihin toimintoihin.
- Emättintukea ei saa jättää emättimeen 4 viikkoa pidemmäksi ajaksi.
- Palloa ei saa jättää emättimeen vuorokautta pidemmäksi ajaksi.
- GYNECARE PROSIMA -järjestelmän osia ei ole tarkoitettu käytettäväksi muiden kuin tässä tuoteselosteessa mainittujen laitteiden kanssa.
- Vältä kiristämistä verkkoinplanttia liikaa käsittelyn aikana.
- Käytä GYNECARE PROSIMA -järjestelmiä varovaisuutta noudattaen ja potilaan anatomia huomioon ottaen verisuonten, hermojen, virtsarakon ja suoliston vaurioiden sekä emätinseinämän perforaation välttämiseksi. GYNECARE PROSIMA -järjestelmän komponenttien oikea käyttö minimoi riskiä.
- Täytä pallo ainoastaan huoneilmalla.
- Palpointi varmistaa, että pallossa ei ole dimavutoja sen täyttämisen jälkeen. Ilman tyhjentymisen kokonaan rajoittaa pallon tehokkuutta.
- Pallon seinämä on ohut toivottujen tulosten aikaansaamiseksi. Punktiot, leikkaaminen, kolhaisuus, puristuminen tai liika paine voi johtaa pallon tyhjentymiseen. Pallo voidaan puhkaista helposti neulalla tai skaipellilla tai se voi revetä, jos sitä käsitellään tyypillä instrumentilla. Vaurioiden estämiseksi palloa on käsiteltävä varovasti. Vaurioitunutta palloa ei saa käyttää. Poista pallo ja käytä pumpulimateriaalia.
- Pallon enimmäistäyttyvyys on 90 ml. Palloa ei saa ylitäyttää. Pallon ylitäyttäminen voi aiheuttaa potilaan epämukavuutta, kudosekroosia, emätinseinämän repeytymistä toimenpiteen jälkeen tai virtsaamiskyvyttömyyttä.
- GYNECARE PROSIMA -järjestelmiä ei saa käyttää potilailla, joille annetaan antikoagulanttiterapiaa.
- Leikkauksen jälkeen voi esiintyä verenvuotoa. Kaikkia oireita tai merkkejä on seurattava ennen kuin potilas kotiutetaan.
- Potilasta on kehoitettava ottamaan välittömästi yhteyttä kirurgiin, jos hänellä esiintyy kipua virtsassa, verenvuotoa tai muita ongelmia.
- Vaikka virtsarakon vaurioituminen on epätodennäköistä tällä menetelmällä käytettäessä, kystoskopiaa suositellaan.
- Vaikka rektaalinen vaurio on epätodennäköistä tällä menetelmällä käytettäessä, tuseerausta suositellaan.
- GYNECARE GYNEMESH PS -verkkoinplantti ei saa koskettaa hakasia, klipsejä tai puristimia, sillä ne voivat aiheuttaa verkon mekaanisia vaurioita.
- Verkkoinplanttia ei saa sijoittaa emättimen ulompaan kolmannekseen. Tarvittaessa verkkoinplanttia on leikattava ulomman kolmanneksen ja keskinäisen kolmanneksen yhtymäkohdasta.
- Profylaktista antibioottilääkitystä voidaan antaa kirurgin normaalin käytännön mukaisesti.

HAITTAVAIKUTUKSET

- Mahdollisia haittavaikutuksia ovat normaalit, kirurgisesti asetettujen materiaalien yhteydessä havaitut haittavaikutukset, mukaan lukien infektion lisääntyminen, tulehdus, kinnikkeiden muodostuminen, fisteleiden muodostuminen, eroosio, ulostyöntyminen ja arpeutuminen aiheutuva implantin supistuminen.
- Mahdollisia haittavaikutuksia ovat normaalisti lantionelinten laskeumien korjaustoimenpiteisiin liitetty haittavaikutukset, mukaan lukien kipu yhdynnän yhteydessä ja lantiokipu. Nämä voivat parantua itsestään ajan kuluessa.
- Dissektion tai verkon sijoittamisen yhteydessä saattaa tapahtua kirurgista korjausta vaativia verisuonien, hermojen, virtsarakon, virtsaputken tai suolen lävistyksiä tai repeämiä.
- Lantionpohjan korjaustoimenpiteissä suoritettavat dissektiot voivat haitata normaalia virtsaamista vaihtelevan pituisen ajan.

STERILIS

GYNECARE PROSIMA -järjestelmät on steriloitu etyleenioksidilla. GYNECARE PROSIMA -järjestelmän mitään osaa EI SAA STERILOIDA UUDELLEEN. GYNECARE PROSIMA -järjestelmän mitään osaa EI SAA KÄYTTÄÄ UUDELLEEN. Tämän laitteen (tai laitteen osien) uudelleenkäyttäminen voi aiheuttaa tuotteen haurastumisen ja likaantumisen, mikä voi johtaa infektsioon tai veren mukana kulkeutuvien patogeenien siirtymisen potilaaseen ja käyttäjään. Ei saa käyttää, jos pakkaus on auki tai vaurioitunut. Hävitä avatut, käyttämättömät GYNECARE PROSIMA -järjestelmän komponentit.








LAITTEEN JA TARVIKKEIDEN HÄVITTÄMINEN

Hävitä GYNECARE PROSIMA -järjestelmän komponentit ja pakkausmateriaalit sairaalan biomateriaaleja ja tartuntatautiolosuhteita koskevien ohjeiden mukaisesti.

SÄILYTYS

Suosittelut säilytysolosuhteet: kontrolloitu huoneen lämpötila ja suhteellinen kosteus (noin 25 °C, 60 % suhteellinen kosteus), etäällä kosteudesta ja suorasta lämmöstä. Ei saa käyttää viimeisen käyttöpäivän jälkeen.

Tuotetietojen symbolit

 <p>0006 CE-merkintä ja sen viranomaisen tunnusnumero, jolle ilmoitus on tehty. Tuote on lääkitönsäistä laitteista annetun direktiivin 93/42/ETY olennaisten vaatimusten mukainen.</p>	 <p>Valmistaja</p>
 <p>Eränumero</p>	 <p>Ei saa käyttää / steriloida uudelleen</p>
 <p>Viimeinen käyttöpäivä — vuosi ja kuukausi</p>	 <p>Lue käyttöohjeet</p>
 <p>Steriloitu etyleenioksidilla</p>	



Système de réparation du plancher pelvien antérieur
Système de réparation du plancher pelvien postérieur
Système de réparation combiné du plancher pelvien

FRANÇAIS

Lire soigneusement toutes les informations.

Le non-respect des instructions d'utilisation peut entraîner un dysfonctionnement du dispositif et engendrer des incidents.

MISE EN GARDE : en vertu de la loi fédérale des États-Unis, le dispositif ne peut être vendu que par un médecin ou sur sa prescription médicale.

Une formation relative à l'utilisation des systèmes de réparation du plancher pelvien GYNECARE PROSIMA™ est disponible et recommandée. Contacter le responsable commercial de la société en vue d'organiser cette formation.

INDICATIONS

Par la mise en place de treillis à mailles souples en PROLENE™ non résorbables GYNECARE GYNEMESH™ PS, les systèmes de réparation du plancher pelvien GYNECARE PROSIMA sont indiqués pour le renforcement des tissus et une stabilisation de longue durée des structures faciales du plancher pelvien. Ces systèmes ont un rôle de support mécanique et/ou de matériau de pontage des défauts faciaux. Ces systèmes assurent le maintien du conduit vaginal durant la période de cicatrisation qui suit la réparation du prolapsus vaginal, tout en maintenant en place les implants en treillis.

DESCRIPTION

Les systèmes de réparation du plancher pelvien, antérieur, postérieur et combiné GYNECARE PROSIMA sont constitués de prothèses prédecoupées de treillis GYNECARE GYNEMESH PS et d'instruments facilitant leur mise en place et leur maintien en post-opératoire (voir figure 1). Le tableau suivant récapitule les composants inclus dans chaque système :

SYSTÈME DE RÉPARATION DU PLANCHER PELVIEN	COMPOSANTS (voir figure 1)				
	Prothèse dans son emballage (A)	Ensemble du dispositif de soutien vaginal et du ballonnet (B&C)	Introducteur antérieur (D)	Introducteur postérieur (E)	Seringue (F)
Antérieur	1	1	1		1
Postérieur	1	1		1	1
Combiné	2	1	1	1	1

Tableau 1 — Composants du système de réparation du plancher pelvien GYNECARE PROSIMA

TREILIS GYNECARE GYNEMESH PS

Le treillis GYNECARE GYNEMESH PS est composé de filaments tricotés de polypropylène extrudés, dont la composition est identique à celle du fil de suture chirurgical PROLENE™ en polypropylène (ETHCON, INC.). Lorsqu'il est utilisé comme fil de suture, ce matériau est rapporté comme non réactif et conserve sa résistance indéfiniment lors d'une utilisation clinique. Le treillis présente une résistance, une durabilité ainsi qu'une bonne adaptabilité chirurgicale, avec une porosité suffisante pour permettre la colonisation tissulaire nécessaire. Des mono-filaments bleus PROLENE sont incorporés dans le treillis pour lui conférer des stries de contraste. Le treillis est composé de fibres mono filamenteuses de diamètre réduit, tricotées selon un modèle unique, avec pour résultat un treillis approximativement 50 % plus souple que le treillis standard PROLENE™ en polypropylène. Le treillis est tricoté selon un procédé qui permet d'obtenir une maille interlock qui lui assure une extensibilité bidirectionnelle. Cette construction fait que le treillis peut être découpé selon la forme et la taille désirées, sans démaillage. Cette extensibilité bidirectionnelle permet une adaptation aux diverses anatomies de l'organisme.

La prothèse

Les prothèses sont fabriquées à partir d'un treillis GYNECARE GYNEMESH PS. Elles sont prédecoupées en forme de Y pour la réparation des déficiences vaginales antérieures, postérieures et/ou apicales. Voir la figure 2. La prothèse possède un corps central et deux bras. Il existe une languette apicale sur l'extrémité proximale de la prothèse pour la maintenir en place par un point de suture et minimiser son déplacement lors de la mise en place des bras. L'écharcure sur l'extrémité distale de la prothèse facilite son alignement. Il existe des poches préformées au sommet des bras pour permettre leur mise en place avec des introducteurs. La prothèse est fournie dans son emballage composé de Tyvek® non recouvert et d'un film plastique transparent, conçu pour un retrait facile de la prothèse.

L'introducteur antérieur

L'introducteur antérieur est un instrument à usage unique, conçu pour faciliter l'insertion des bras de la prothèse dans les tunnels tissulaires antérieurs préalablement disséqués. **REMARQUE : l'introducteur antérieur n'est pas indiqué pour la dissection des tissus.** Il est conçu pour être compatible avec les poches situées au sommet des bras de la prothèse afin de faciliter leur mise en place des deux côtés de la patiente, dans le compartiment antérieur. Voir les figures 3 et 4.

L'introducteur postérieur

L'introducteur postérieur est un instrument à usage unique, conçu pour faciliter l'insertion des bras de la prothèse dans les tunnels tissulaires postérieurs préalablement disséqués. **REMARQUE : l'introducteur postérieur n'est pas indiqué pour la dissection des tissus.** En vue d'une insertion contrôlée, un conducteur/poche-aiguille se fixe sur l'introducteur postérieur en tant que stabilisateur. L'introducteur postérieur est conçu pour être compatible avec les poches situées au sommet des bras de la prothèse afin de faciliter leur mise en place des deux côtés de la patiente, dans le compartiment postérieur. Voir la figure 5.

Le dispositif de Support Vaginal (DSV)

Le DSV est un dispositif à usage unique, conçu pour conférer un support post-opératoire aux tissus vaginaux après la mise en place du treillis et la fermeture des incisions vaginales. Son extrémité apicale est l'extrémité la plus large possédant des sections découppables. Après une mesure des dimensions intérieures de la patiente, la taille du DSV est ajustée pour l'adapter à l'anatomie de la patiente en coupant aux niveaux les sections apicales pré-marquées du DSV. Ce dernier est logé dans les 2/3 supérieurs du vagin pendant 3 à 4 semaines, puis il en est retiré. Voir la figure 6.

Le ballonnet

Le ballonnet est un dispositif à usage unique, conçu pour remplacer la garniture de gaze vaginale post-opératoire. Le volume du ballonnet est ajustable afin de remplir le conduit vaginal et pour que la paroi vaginale serve de contrefort à la prothèse. Le ballonnet est fourni pré-attaché au DSV. La figure 7 montre le ballonnet dégonflé, sans attache au DSV. Le ballonnet reste en place pendant un jour au maximum.

La seringue

Une seringue de 50 ml est fournie pour gonfler le ballonnet.

SECTION 1 : PRINCIPES D'UTILISATION DU SYSTÈME GYNECARE PROSIMA

La réparation du plancher pelvien antérieur utilisant le système GYNECARE PROSIMA vise à réaliser une réparation anatomique durable et standardisée du prolapsus d'un organe pelvien. En fonction de la localisation du prolapsus et des préférences du chirurgien, la réparation est antérieure et/ou postérieure. Une hystérectomie ou une conservation utérine peuvent être associées à l'utilisation du système GYNECARE PROSIMA. Si cela est indiqué pour traiter une incontinence urinaire d'effort, une réparation périméale ou la pose d'une bandelette sous-urétrale peuvent être réalisées en même temps que l'intervention utilisant le système GYNECARE PROSIMA. On peut utiliser une bandelette rétropubienne ou sous-urétrale trans-cicatricielle.

La réparation du prolapsus est réalisée grâce à la mise en place par voie vaginale d'une ou de deux prothèses. À la fin de l'intervention, un DSV avec ballonnet gonflable est introduit dans le vagin pour la prise des dimensions, puis le DSV est suturé sur place, maintenant ainsi le vagin et la prothèse (ou les prothèses) durant la colonisation tissulaire à l'intérieur des mailles. Une fois gonflé, le ballonnet remplace la traditionnelle garniture en gaze en remplissant la cavité vaginale et fait jouer au vagin le rôle de contrefort pour la prothèse (ou les prothèses). Un jour après la chirurgie, le ballonnet est dégonflé et retiré du vagin sans déloger le DSV. Ce dernier reste en place pendant un maximum de 4 semaines après la chirurgie, tandis que la colonisation tissulaire se fait à l'intérieur des mailles de la prothèse (ou des prothèses).

SECTION 2 : LE PRINCIPE DU PROCÉDÉ GYNECARE PROSIMA

À la suite d'une chirurgie conventionnelle pour prolapsus d'un organe pelvien, les tissus réparés sont exposés à une augmentation de la pression intra-abdominale dans la mesure où la patiente se mobilise, tousse, vomit et pousse pour évacuer son gros intestin. Tout ce qui accroît la pression intra-abdominale peut affecter la cicatrisation de la réparation vaginale et déboucher sur un échec chirurgical et une récidive du prolapsus. En renforçant la réparation vaginale par une prothèse et en maintenant le vagin à l'aide du DSV durant les 3 à 4 semaines qui suivent l'intervention, le recours au système GYNECARE PROSIMA est conçu pour réduire le risque d'échec chirurgical et de récidive du prolapsus.

Lors d'une réparation antérieure du vagin, le corps de la prothèse doit être positionné sans tension entre la vessie et les 2/3 supérieurs du vagin, tout en s'étendant latéralement à l'arc tendineux du fascia pelvien. Lors d'une réparation postérieure du vagin, le corps de la prothèse doit être placé sans tension entre le rectum et les 2/3 supérieurs du vagin, en s'ajustant latéralement au-dessus des muscles élévateurs de l'anus. La section apicale du corps de la prothèse doit atteindre le sommet du vagin. En avant, la prothèse peut s'appliquer sur le tissu pré-vésical ou sur le col grâce à un point de bâti. En arrière, la prothèse peut s'appliquer sur le tissu pré-rectal ou le col.

Après la chirurgie, le DSV soutient les tissus du vagin et fait jouer aux tissus vaginaux le rôle d'arc-boutant pour la prothèse jusqu'à ce que la colonisation tissulaire se réalise à l'intérieur de ses mailles. La colonisation tissulaire à l'intérieur de la prothèse débute au cours des 3 à 4 semaines qui suivent la chirurgie. L'utilisation du système GYNECARE PROSIMA évite une dissection à l'extérieur de la cavité péelvienne et le passage de sutures et d'instruments à travers le foramen obturateur et le ligament sacro-épineux, rendant ainsi la chirurgie plus facile à réaliser.

Hystérectomie

Les préférences du chirurgien et les besoins de la patiente déterminent l'opportunité d'une hystérectomie concomitante. Lorsque cette dernière est décidée, la fermeture du cul-de-sac péritonéal est recommandée afin d'éviter un contact entre le treillis et l'intestin. La fermeture d'une incision en « T » doit être évitée, car elle augmente le risque d'exposition du treillis. Lorsqu'une hystérectomie par voie vaginale est effectuée en même temps qu'une réparation antérieure et/ou postérieure, l'incision d'hystérectomie doit d'abord être fermée transversalement. C'est ensuite que les incisions de réparation peuvent être faites de telle façon qu'elles n'aient aucun point d'intersection avec l'incision d'hystérectomie déjà refermée. Cette technique empêche la création d'une incision en « T ».

Conservation utérine

L'utilisation du système GYNECARE PROSIMA convient aux situations où le chirurgien ou la patiente ont décidé de conserver l'utérus.

Incisions vaginales

Lors de la technique GYNECARE PROSIMA, les incisions vaginales sont les mêmes que celles pratiquées par le chirurgien lors d'une réparation vaginale de routine. Ces incisions doivent être faites à travers la paroi la plus profonde du vagin afin de réduire au maximum la possibilité d'exposition du treillis.

Mise en place de la prothèse

Les prothèses sont maintenues en place par le DSV jusqu'à ce que la colonisation tissulaire se réalise. Raison pour laquelle il est inutile de fixer les bras de la prothèse lorsqu'ils sont en place. La partie apicale de la prothèse peut être appliquée par un point de bâti sur la ligne médiane du dôme vaginal, grâce à un fil de suture de type MONOCRYL™ 2-0 (poliglecaprone 25) ou Coated VICRYL™ 2-0 (polyglactine 910). Toutefois, l'épithélium vaginal ne doit pas être suturé à la prothèse.

Préservation du vagin

Le retrait ou l'excision d'un excès d'épithélium vaginal doit être évité en raison d'un risque de rétraction tissulaire postopératoire. Une capacité vaginale réduite peut encore s'aggraver lorsque trop d'épithélium vaginal a été enlevé.

Trois niveaux de support vaginal

Pour une réparation vaginale, il existe 3 niveaux de supports vaginaux bien connus. L'utilisation du système GYNECARE PROSIMA répond aux niveaux I et II de ces supports, de la façon suivante :

Niveau I – Suspension et support (tiers supérieur du vagin)

Le tiers supérieur du vagin (y compris la voûte après une hystérectomie) et l'utérus sont soutenus par deux mécanismes. Le premier, un support direct à l'utérus et à la partie supérieure du vagin fournis par des paramètres (ligaments cardinaux et utéro-sacrés) et des fibres para-cervicales. Ces fibres agissent comme des ligaments suspenseurs et proviennent du fascia du muscle piriforme, de l'articulation sacro-iliaque et des bords du sacrum. Elles s'insèrent sur le tiers supérieur latéral du vagin et sur la face postéro-latérale du col. Le second, un support indirect de l'utérus et du vagin apporté par la plaque élastique constituée par la fusion des muscles éleveurs droits et gauches de l'anus, situés entre le rectum et le coccyx. Le prolapsus de la voûte vaginale et de l'utérus est la conséquence d'une insuffisance de ces mécanismes de support, directs et indirects. Cette insuffisance est due à une faiblesse des muscles du plancher pelvien, des fibres suspensives des paramètres et des fibres para-cervicales supérieures. Le but de la chirurgie de niveau I du prolapsus est de reconstituer ces mécanismes de support direct et indirect. Le système GYNECARE PROSIMA répond à ces exigences en mettant les bras de la prothèse en contiguïté avec chaque muscle obturateur interne et en recouvrant le fascia latéral, lors d'une réparation vaginale antérieure, et en mettant les bras de la prothèse en contiguïté avec les ligaments sacro-épineux lors d'une réparation vaginale postérieure. Ces techniques confèrent un support direct grâce à une suspension et un support indirect grâce à la prothèse qui réalise une large zone de support pour la partie supérieure du vagin et pour l'utérus.

Niveau II – Fixation latérale (tiers moyen du vagin)

Le milieu du vagin est fixé directement et latéralement aux muscles de la paroi latérale du pelvis par l'arc tendineux du fascia pelvien. À ce niveau, les parois antérieure et postérieure du vagin sont tendues entre des attaches latérales, droites et gauches. Au niveau II, la réparation d'un prolapsus vise à rattacher la partie moyenne latérale du vagin aux muscles des parois latérales du pelvis. Les déficiences centrales du milieu du vagin nécessitent également un support de niveau II. L'utilisation du système GYNECARE PROSIMA rétablit les attaches latérales du vagin aux muscles des côtés du pelvis ; il procure également un renforcement central du fascia à la suite de la colonisation tissulaire à l'intérieur des mailles de la prothèse.

Niveau III – Fusion (tiers inférieur du vagin)

REMARQUE : la dissection de cette région n'est pas nécessaire lors de l'utilisation du système GYNECARE PROSIMA. Au niveau III, le tiers inférieur du vagin fusionne en avant avec la membrane périnéale et l'urètre. En arrière, il fusionne avec le corps du périnée et les muscles éleveurs de l'anus. Dans cette région, les tissus sont réparés sans prothèse, car celle-ci n'est pas prévue pour le tiers inférieur du vagin. Le système GYNECARE PROSIMA n'est pas indiqué aux déficits de soutien de niveau III, bien que ces déficits puissent faire l'objet d'un acte chirurgical simultané, telle une périnéorraphie.

SECTION 3 : MODE D'EMPLOI

REMARQUE : les figures présentées au début du document doivent être référencées lors de la lecture de cette section.

Préparation chirurgicale

La chirurgie effectuée grâce à l'utilisation du système GYNECARE PROSIMA peut être réalisée sous anesthésie générale ou locale, en fonction des préférences du chirurgien, de l'anesthésiste et de la patiente.

La patiente doit être en position gynécologique, avec les fesses légèrement en surplomb de la table d'opération et les hanches flechées. À la discrétion du chirurgien, la vessie peut être vidée ou un cathéter est mis en place.

Le système GYNECARE PROSIMA en post-hystérectomie

Réparation vaginale antérieure

Lorsque le renforcement de la paroi antérieure du vagin seule s'avère nécessaire, il ne doit être utilisé que le système de réparation du plancher pelvien antérieur GYNECARE PROSIMA. Celui-ci contient une prothèse et un introducteur antérieur spécialement conçu pour la réparation vaginale antérieure. Une fois que les incisions et dissections vaginales sont faites, des tunnels tissulaires sont créés dans le compartiment antérieur pour la mise en place des bras de la prothèse en utilisant l'introducteur antérieur. **REMARQUE : l'introducteur antérieur ne doit pas être utilisé pour la dissection des tissus.**

Dissection vaginale antérieure

L'épithélium vaginal antérieur est disséqué et séparé de la vessie. La pleine épaisseur de la paroi vaginale doit être disséquée. Cette dissection doit être facilitée par une hydro-dissection sous épithéliale. La dissection superficielle de la paroi vaginale ou sa séparation en deux plans est à éviter. Une telle dissection peut donner lieu à une paroi vaginale très fine et peut également compromettre la vascularisation de la paroi vaginale, augmentant ainsi le risque d'exposition du tréillis. Latéralement, la dissection continue jusqu'aux parois du pévis et l'épine ischiatique.

Dissection des tunnels antérieurs et pose de la prothèse

Pour les besoins de cette description, la dissection créant les tunnels destinés aux bras de la prothèse est d'abord réalisée sur le côté droit de la patiente, puis sur le côté gauche. Ces tunnels sont créés pour mettre en place la prothèse de telle façon que la section distale des bras s'aligne sur la paroi latérale du pelvis et sur le fascia pariétal du muscle obturateur interne. Pour mettre en place ces bras, la dissection doit être préchée des deux côtés par la palpation et l'identification de l'épine ischiatique. **REMARQUE : cette dissection peut commencer avec des ciseaux selon une technique de « tâtouement étalé », de telle façon que le bout des ciseaux reste toujours en avant de l'épine ischiatique.** La dissection initiale est suivie d'une prudente dissection au doigt jusqu'à l'épine ischiatique. Une fois le contact obtenu avec l'épine ischiatique, créer avec l'index un espace en avant et au-dessus de l'épine ischiatique. Voir la figure 8A. La dissection, qui est perpendiculaire à la paroi latérale du pévis, crée un espace d'environnement 2 cm de large et 3 cm de haut. Cette dissection antérieure ne va pas jusqu'aux ligaments sacro-épineux. Elle crée un tunnel en avant et au-dessus de l'épine ischiatique et superficiel à l'arc tendineux du fascia pelvien, au muscle obturateur interne et à son fascia latéral. Une dissection identique est répétée du côté gauche.

Le plessissement du tissu pré-vesical n'est pas nécessaire. Toutefois, si celui-ci est effectué, il ne concerne que sa partie centrale. Il évite que la région disséquée soit trop étroite. Placer la prothèse sur le tissu pré-vesical, en faisant en sorte que les poches des bras de l'implant regardent vers le haut. Si un faufilage doit être réalisé, il convient de le faire à ce moment de l'intervention avec une suture de type MONOCRYL 2-0 ou Coated VICRYL 2-0 revêtue, posée au sommet du vagin et passant par la languette apicale de la prothèse. Le point de suture peut être attaché à ce moment-là ou après que les bras soient en place. Le faufilage de l'échancrure distale de la prothèse est facultatif. Il peut être réalisé avec du fil de suture de type MONOCRYL 2-0 ou Coated VICRYL 2-0 revêtue.

En utilisant l'introducteur antérieur, placer les deux bras de l'implant dans les tunnels droit et gauche qui ont été créés par dissection antéro-supérieure allant jusqu'à l'épine ischiatique (tel que décrit ci-dessus). **REMARQUE : les deux extrémités courbées de l'introducteur antérieur sont tournées dans des directions opposées, avec des flèches sur chacune d'elles indiquant la direction du positionnement.** Avec la flèche pointant vers le côté droit de la patiente, introduire l'extrémité de l'introducteur antérieur dans la poche du bras de la prothèse (voir la figure 8B) située sur le côté droit. **REMARQUE : une traction sur le contrefort peut aider à maintenir la poche sur l'introducteur antérieur.** Garder l'introducteur antérieur en position verticale, de telle façon que la partie courbe de l'instrument soit contre la paroi postérieure du vagin. L'introducteur antérieur qui entraîne le bras est ensuite dirigé vers le tunnel tissulaire précédemment créé (voir la figure 8C) jusqu'à ce que le manche entre en contact de la grande lèvre controlatérale. Tout ceci est accompli en dirigeant le manche de l'introducteur antérieur verticalement et vers le haut, de telle façon que le bord conducteur et la poche aillent en direction de l'épine ischiatique. Une fois positionné, le

manche est alors incliné vers le bas jusqu'à une position presque horizontale, tout en maintenant le manche en contact avec la cuisse controlatérale. **REMARQUE : le fait de rétracter la vessie avec un instrument chirurgical standard peut aider au placement initial dans le tunnel. Si nécessaire, introduire un index dans le tunnel pour guider le positionnement initial de l'introducteur antérieur contre la grande lèvre controlatérale, avant d'abaisser le manche.** Une légère poussée vers le haut assure que la poche du bras est positionnée correctement et que la section apicale de la prothèse est en contiguïté avec le sommet du vagin. **REMARQUE : si une résistance est ressentie durant l'insertion du bras, en déterminer la cause avant de continuer. Le fait de continuer à faire avancer l'introducteur contre une résistance peut détériorer la prothèse, ou provoquer une insertion forcée causant des lésions à des structures tissulaires essentielles.**

Pour retirer l'introducteur antérieur, ramener le manche vers une position verticale avant de le retirer, tout en laissant le bras dans le tunnel. **REMARQUE : insérer complètement le premier bras. REMARQUE : si l'introducteur antérieur est retiré avant que le bras soit positionné dans sa cible, le bras devra être retiré, rechargé sur l'introducteur et réinséré.** Tous ces gestes sont répétés sur le côté opposé de la patiente. Ainsi, après avoir retourné l'introducteur antérieur, la flèche pointe maintenant du côté gauche. On insère cette extrémité de l'introducteur dans l'autre poche. La figure 8D montre les deux bras en place. **REMARQUE : lors du positionnement du second bras, éviter de déplacer la prothèse et s'assurer que la prothèse N'EST PAS tordue.**

Le corps de la prothèse est lâchement posé sur le tissu vaginal sous-jacent. Le plessissement ou l'entortillement du corps et des bras doit être évité. Le corps de la prothèse peut nécessiter un découpage qui dépend des dimensions vaginales ou de l'importance de la dissection latérale. L'épithélium vaginal peut être taillé, mais un retrait excessif d'épithélium doit être évité. L'épithélium se referme au-dessus de la prothèse sans recourir à des points de suture qui se chevauchent (tels que décrits ci-dessous sur la figure 8E). La mise en place définitive de la prothèse dans le compartiment antérieur est montrée sur la figure 8F.

REMARQUE : s'assurer que l'hémostase est effective avant et durant la fermeture des incisions vaginales.

Les incisions vaginales sont fermées sans sutures chevauchantes ou en huit. Cette technique évite la dévascularisation de l'épithélium vaginal le long des lignes d'incision et réduit la dégradation du tréillis. De préférence, l'épithélium vaginal est reformé en deux plans afin d'obtenir une ligne de suture relativement épaisse en regard de l'incision vaginale. Le plan le plus profond est fermé par des points de suture sous-épithéliaux en surjet, ne se chevauchant pas, avec du fil de suture de type MONOCRYL 2-0 ou MONOCRYL Plus™ 2-0 antibactérien (polyglactine 25). L'épithélium est ensuite reformé par un surjet fait de points de matelas alternés, avec du fil de suture de type Coated VICRYL 2-0 revêtu ou Coated VICRYL Plus™ 2-0 revêtu antibactérien (polyglactine 910). **REMARQUE : placer la prothèse sur les 2/3 supérieurs du vagin, en prenant soin de découper la prothèse si elle descend en dessous des 2/3 supérieurs.** Si ce n'est déjà fait, une cystoscopie est recommandée pour exclure toute lésion de l'arbre urinaire.

Comme alternative, la fermeture en un seul plan de la paroi vaginale peut être effectuée. On peut utiliser un surjet fait de points de matelas alternés, sans chevauchement, ou des points séparés, faits de Coated VICRYL 2-0 revêtu ou de Coated VICRYL Plus 2-0 revêtu.

Réparation vaginale postérieure

Lorsque seul le renforcement de la paroi postérieure du vagin est nécessaire, on n'a recouru qu'au seul système de réparation du plancher pelvien postérieur GYNECARE PROSIMA. Ce dernier comprend une prothèse et un introducteur postérieur spécialement conçu pour les réparations vaginales postérieures. Une fois les incisions vaginales et les dissections requises exécutées, des tunnels tissulaires sont créés dans le compartiment postérieur pour la mise en place des bras de la prothèse. **REMARQUE : l'introducteur postérieur ne doit pas être utilisé pour la dissection des tissus.**

Dissection vaginale postérieure et dissection des tunnels

L'épithélium vaginal postérieur est disséqué jusqu'au tissu pré-rectal. Comme pour la paroi antérieure du vagin, la pleine épaisseur de la paroi postérieure doit être disséquée. Cette dissection est facilitée par une hydro-dissection sous-épithéliale. Latéralement, la dissection se poursuit des deux côtés jusqu'aux muscles éleveurs de l'anus, au niveau de l'épine ischiatique. En arrière, la dissection se poursuit à travers chacun des deux piliers du rectum jusqu'aux ligaments sacro-épineux, mais non à travers ces ligaments. De cette façon, sont créés des tunnels dans lesquels se logeront les bras de la prothèse. Voir la figure 9A.

La prise en charge d'une entéroécie préexistante est facultative ; mais si elle est réalisée, elle peut être effectuée à ce stade de l'intervention selon la technique choisie par le chirurgien.

Si la cavité péritonéale est ouverte lors de la dissection antérieure ou postérieure, elle doit être refermée avant la mise en place de l'implant.

Mise en place de la prothèse postérieure

Le plessissement du tissu pré-rectal n'est pas nécessaire. Toutefois, si le plessissement du tissu pré-rectal est effectué, seule sa partie centrale en fait l'objet. Cela évite que la zone de dissection ne soit trop étroite. Placer la prothèse sur le tissu pré-rectal, avec les poches des bras tournées vers le haut. Si un point doit être posé, il doit l'être à ce stade de l'intervention, en plaçant une suture au sommet du vagin, qui passe par la languette apicale de la prothèse, avec un fil de suture de type MONOCRYL 2-0 ou Coated VICRYL 2-0 revêtu. Le point peut être serré à ce moment-là ou une fois que les bras sont en place. Bâter un point sur l'échancrure distale de la prothèse est facultatif. Cela peut être exécuté avec un fil de suture de type MONOCRYL 2-0 ou Coated VICRYL 2-0 revêtu.

En utilisant l'introducteur postérieur, placer les bras postérieurs de l'implant dans les tunnels droit et gauche, créés par la dissection allant jusqu'à chacun des deux ligaments sacro-épineux (comme décrit ci-dessus). Saisir l'introducteur postérieur en utilisant un conducteur/porte-aiguille droit, comme indiqué sur la figure 9B. **REMARQUE : placer l'extrémité du porte-aiguille à l'intérieur de l'extrémité cannelée et droite de l'introducteur postérieur.** S'assurer que l'introducteur postérieur est bien aligné sur le manche du porte-aiguille. Insérer l'extrémité de l'introducteur postérieur dans la poche du bras destinée au côté droit de la patiente (voir la figure 9B). Une fois que le bras est accolé à l'introducteur postérieur, introduire ce dernier dans le tunnel tissulaire créé à cet effet (voir la figure 9C), en tenant verticalement le manche du conducteur/porte-aiguille. Continuer d'introduire la totalité du bras dans son tunnel, de telle façon que la base du bras soit à la hauteur de la limite supérieure de la dissection faciale.

REMARQUE : insérer complètement le premier bras. Si l'introducteur est retiré avant que le bras n'ait atteint sa cible, le bras devra être retiré, rechargé et réinséré. REMARQUE : faire attention à ne pas introduire trop profondément l'introducteur pour éviter d'endommager des structures tissulaires critiques. REMARQUE : si une résistance est ressentie lors de l'introduction, en trouver la cause avant de continuer. Le fait de continuer à avancer l'introducteur contre la résistance peut provoquer la détérioration de la prothèse ou une insertion trop profonde causant des lésions à des structures tissulaires critiques. L'introducteur postérieur est retiré le long de la voie d'introduction en laissant en place le bras dans le tunnel. Les bras touchent les ligaments sacro-épineux, mais n'y pénètrent pas. Les sutures ne doivent pas être placées sur les ligaments sacro-épineux. Pour le second bras, répéter la même procédure sur le côté gauche de la patiente. La figure 9D montre les deux bras en place. **REMARQUE : lors du positionnement du second bras, éviter de déplacer la prothèse et s'assurer que la prothèse N'EST PAS tordue.**

Le corps de la prothèse est mis en place sans tension au-dessus du fascia vaginal sous-jacent. Le franchement ou l'entortillement du corps de la prothèse ou des bras est à éviter. En fonction des dimensions vaginales ou de l'étendue de la dissection latérale, la prothèse peut demander à être raccourcie. L'épithélium de la paroi postérieure du vagin peut être découpé, mais une ablation excessive doit être évitée. L'épithélium de la paroi postérieure est refermé au-dessus de la prothèse, sans recourir à des sutures qui se chevauchent (comme il est indiqué plus haut). Le positionnement définitif de la prothèse dans le compartiment postérieur est montré sur la figure 9E.

REMARQUE : s'assurer que l'hémostasie est réalisée avant et durant la fermeture des incisions vaginales.

Les incisions vaginales seront refermées sans recourir à des sutures se chevauchant ou en haché. Cette technique évite une dévascularisation de l'épithélium vaginal le long des lignes d'incision et réduit la détérioration de la prothèse. De préférence, l'épithélium est refermé en deux plans afin d'obtenir une ligne de suture relativement épaisse en regard de l'incision vaginale. La couche la plus profonde est refermée en utilisant un surjet fait de points sous-épithéliaux ne se chevauchant pas, avec du fil de suture de type MONOCRYL 2-0 ou MONOCRYL Plus 2-0 antibactérien. L'épithélium est ensuite refermé par un surjet fait de points de suture de matelas alternés et ne se chevauchant pas, en utilisant du fil de suture de type Coated VICRYL 2-0 revêtu ou Coated VICRYL Plus 2-0 revêtu. **REMARQUE : placer la prothèse sur les 2/3 supérieurs du vagin, en prenant soin de couper la prothèse si elle descend en dessous des 2/3 supérieurs.** À la fin de la chirurgie, un toucher rectal élimine une lésion rectale.

Comme alternative, on peut effectuer la fermeture de la paroi vaginale en un seul plan. On utilise un surjet fait de points de suture de matelas alternés et sans chevauchement, ou des points espacés, avec du fil de suture de type Coated VICRYL 2-0 revêtu ou Coated VICRYL Plus 2-0 revêtu.

Réparation vaginale combinée antérieure et postérieure

Lorsque le renforcement des deux parois vaginales antérieure et postérieure est nécessaire, c'est une indication du système combiné du plancher pelvien GYNECARE PROSIMA. Ce dernier contient deux prothèses identiques, l'une pour la réparation vaginale antérieure, l'autre pour la réparation vaginale postérieure. N'utiliser que l'introducteur antérieur incurvé pour la réparation antérieure, et uniquement l'introducteur postérieur droit pour la réparation postérieure. Les deux réparations antérieure et postérieure sont conduites comme décrit ci-dessus. Il est recommandé que la réparation vaginale antérieure soit réalisée en premier. La mise en place définitive des prothèses dans les deux compartiments antérieur et postérieur est illustrée sur la figure 10. Après la chirurgie, une cystoscopie est recommandée pour éliminer une blessure de l'arbre urinaire. Un toucher rectal élimine une blessure du rectum.

La technique GYNECARE PROSIMA avec conservation utérine (hystéropexie)

Si l'utérus prolabé doit être conservé, la languette apicale de la prothèse doit être fixée au col. Cette fixation de la prothèse au col de l'utérus doit se faire au niveau de l'anneau cervico-pubien lorsqu'il est placé durant la réparation vaginale antérieure et postérieure.

Lorsque l'utérus est conservé lors d'une réparation vaginale antérieure, l'anneau cervico-pubien est exposé durant la dissection vaginale antérieure. Une suture PROLENE 2-0 est fermement posée sur la face antérieure de l'anneau cervico-pubien. Une suture est également posée sur la languette apicale de la prothèse. La suture PROLENE de la languette est serrée une fois que les bras de la prothèse sont en place. Le procédé solidarise la prothèse à la surface vaginale postérieure. Un point de suture PROLENE 2-0 est solidement posé sur la face postérieure de l'anneau. Une suture est également posée sur la languette apicale de la prothèse. La suture PROLENE est alors serrée une fois que les bras de la prothèse sont en place. De la sorte, la prothèse est solidement ancrée à la face postérieure du col au niveau de l'anneau cervico-pubien.

S'agissant de la réparation postérieure, la prothèse doit être fixée à la face postérieure du col, au niveau de l'anneau cervico-pubien ou au-dessus. Le cul-de-sac peut être ouvert lors de la fixation de la prothèse au col. Le péritoine du cul-de-sac est refermé au-dessus de cette fixation pour empêcher l'intestin d'adhérer à la prothèse. Si le chirurgien décide de ne pas ouvrir le cul-de-sac, l'anneau cervico-pubien est exposé lors de la dissection vaginale postérieure. Un point de suture PROLENE 2-0 est solidement posé sur la face postérieure de l'anneau. Une suture est également posée sur la languette apicale de la prothèse. La suture PROLENE est alors serrée une fois que les bras de la prothèse sont en place. De la sorte, la prothèse est solidement ancrée à la face postérieure du col au niveau de l'anneau cervico-pubien.

Lorsqu'elles sont utilisées pour les deux réparations antérieure et postérieure, les prothèses doivent être fixées aux deux faces antérieure et postérieure du col, comme décrit ci-dessus (voir la figure 11).

Hygiène des prothèses

Pendant l'intervention, les plaies vaginales doivent être irriguées avec du sérum physiologique. La manipulation des prothèses doit être minimale et une bonne hygiène des treillis doit être respectée.

Mise en place du DSV et du ballonnet

À la fin de la chirurgie, un DSV de taille appropriée, associé à un ballonnet, est mis en place dans le vagin et suturé dans une position où il ne peut se détacher. Le DSV ayant trois tailles possibles (petite, moyenne et large), il est formé par le chirurgien de la façon suivante, afin d'épouser la profondeur vaginale de la patiente :

Formage et découpage du DSV

Le DSV est fourni dans sa taille la plus large. Chez une patiente, on détermine la taille appropriée du DSV en utilisant le DSV lui-même pour évaluer son adaptation. On place la taille la plus large du DSV dans le vagin, entre le dième distendu et l'anneau hyménal. Pour introduire le DSV dans le vagin, saisir le dispositif à son niveau le plus large et le replier le long de son axe longitudinal avec le ballonnet vers le haut (voir la figure 12). La partie la plus large du DSV est introduite en premier de façon à ce que les trous de suture soient situés juste au-dessus de l'anneau hyménal.

REMARQUE : ne pas retirer ou endommager le ballonnet durant l'évaluation de la taille du DSV. La taille adéquate est obtenue lorsque le DSV se loge parfaitement dans les 2/3 supérieurs du vagin distendu, l'extrémité distale et les œillets pour suture étant 1 cm au-dessus de l'anneau hyménal (voir la figure 13).

Si la taille large convient, le DSV n'est pas modifié. Si c'est la taille moyenne qu'il faut, la section la plus haute est retirée en la découpant soigneusement, uniquement avec l'extrémité incurvée de ciseaux de Mayo afin de retirer des petits morceaux et s'assurer d'un bord de coupe régulier. Il faut veiller à minimiser la quantité de matériel restant dans les zones de coupe. **REMARQUE : il est important de bien formater le DSV. Une fois qu'il est coupé, il ne peut plus être élargi, car les sections de coupe ne peuvent pas être recollées.** Le ballonnet doit être écarté du passage pendant le découpage (voir la figure 14). **Faire attention à ne pas endommager le ballonnet lors du découpage du DSV.**

Si la taille moyenne convient, aucun autre découpage n'est nécessaire. S'il faut la petite taille, alors la section restante est retirée de la même façon que la précédente. Le ballonnet sera écarté du passage pendant cet autre découpage afin de ne pas être endommagé.

Une fois que le DSV a la taille adéquate et que le ballonnet est repositionné, l'ensemble peut être introduit dans le vagin de la patiente. **REMARQUE : pour minimiser la possibilité de perforer le ballonnet, n'utiliser aucun instrument pour faciliter l'introduction du DSV et du ballonnet.** Si le ballonnet venait à être endommagé, détacher le ballonnet du DSV et utiliser une garniture de gaze pour remplir la cavité vaginale.

Une fois que l'ensemble est positionné dans les 2/3 supérieurs du vagin distendu de la patiente, le DSV est soigneusement fixé en place par de simples sutures passant par les deux œillets du DSV et prenant l'épithélium de la paroi postérieure du vagin latéralement et au-dessus de l'hymen et sur chaque côté, comme le montre la figure 15 à 4 et 8 heures. Les sutures droite et gauche sont alors serrées, maintenant fermement le DSV en place à l'intérieur du vagin. **REMARQUE : faire attention à ne pas piquer le ballonnet lors de l'annarage du DSV.** Pour cette application, on recommande un fil de suture de type Coated VICRYL 2-0 revêtu ou son équivalent resorbable.

Gonflage du ballonnet

Une fois le DSV suture en position, la seringue de 50 ml, qui est fournie, est fixée par une rotation à la fermeture de la valve du ballonnet. **REMARQUE : après la mise en place du DSV, un cathéter est nécessaire pour éviter la rétention urinaire.** Après gonflage par un petit volume d'air ambiant (voir la figure 16), la tonqueur totale du ballonnet sera palpée avec un index pour s'assurer que le ballonnet est déployé et qu'il occupe la totalité du vagin. Une fois le déploiement confirmé, retirer le doigt et continuer à gonfler à plein le ballonnet jusqu'à ce que l'espace entre le ballonnet et la paroi du vagin ait la largeur de l'extrémité d'un doigt. La stabilisation du DSV est recommandée au fur et à mesure du gonflage. Le ballonnet une fois gonflé sert à appliquer la prothèse sur la paroi vaginale. Le volume d'air nécessaire pour gonfler suffisamment le ballonnet varie d'une patiente à l'autre. **REMARQUE : le volume maximal de gonflage du ballonnet ne doit pas dépasser 90 mL.** Une fois le ballonnet correctement gonflé, la seringue est retirée de la valve en tournant. La tubulure de gonflage du ballonnet doit pouvoir sortir du vagin pour être apposée à la cuisse de la patiente. Le bouchon doit être fixé à la valve du ballonnet pour être sûr que le ballonnet garde le volume d'air prévu (voir la figure 7). **REMARQUE : ne pas trop serrer le bouchon.** Si nécessaire, le volume du ballonnet pourra être réajusté secondairement en utilisant une seringue standard pour augmenter ou diminuer le volume d'air à l'intérieur du ballonnet. À tout moment, le ballonnet peut être palpé ou inspecté visuellement pour s'assurer qu'il garde un gonflage suffisant. **REMARQUE : comme la patiente bouge, le ballonnet se tasse dans la cavité vaginale, et sa pression peut sembler augmenter ou baisser. Ceci est normal.**

REMARQUE : ne pas détacher le ballonnet du DSV avant son utilisation.

REMARQUE : ne pas gonfler le ballonnet avant son introduction dans le vagin.

REMARQUE : après le gonflage du ballonnet, si les œillets de suture du DSV se sont déplacés de plus de 1 cm au-dessus de l'anneau hyménal ou si une tension excessive s'exerce sur les œillets, il faut diminuer la pression du ballonnet, et au besoin repositionner ou reformater le DSV.

REMARQUE : NE PAS utiliser ce ballonnet si des trous sont relevés sur le ballonnet ou si une fuite est détectée, ou si le ballonnet ne peut rester dilaté après son gonflage. Il devra être détaché du DSV et jeté par un moyen adapté. Utiliser à sa place une garniture standard en gaze.

REMARQUE : si la prise de connexion du ballonnet se détache du DSV, il faut la remettre en place.

REMARQUE : ne pas tasser la tubulure de gonflage dans la cavité vaginale.

REMARQUE : pour prévenir toute détérioration, ne jamais appliquer de trop grandes forces de courbure, de tension, ou de torsion sur la tubulure de gonflage.

REMARQUE : ne pas mettre en place une garniture de gaze lorsque le ballonnet est présent.

Détachement du ballonnet du DSV

Grâce à une seringue standard, le ballonnet est complètement dégonflé 1 jour après la chirurgie et retiré, laissant le DSV en place. **REMARQUE : ne pas laisser le ballonnet plus d'une journée dans le vagin.**

1) Retirer le bouchon de la valve du ballonnet.

2) Fixer une seringue standard de 50 ml (ou plus) sur la valve du ballonnet et dégonfler complètement le ballonnet (voir la figure 17). Il est important de le dégonfler entièrement avant de le détacher du DSV. **REMARQUE : un ballonnet totalement dégonflé provoque une rétraction du piston de la seringue après l'aspiration complète de l'air.**

3) Retirer la seringue.

4) Le ballonnet peut alors être séparé du DSV en tirant doucement sur la tubulure de gonflage, à un endroit proche de la prise de connexion du ballonnet, tout en exerçant avec un doigt une contre-pression sur l'extrémité distale du DSV. Voir la figure 18.

REMARQUE : ne retirer le ballonnet que s'il est complètement dégonflé et qu'aucune résistance n'est ressentie.

S'il existe une résistance, en déterminer la cause avant de continuer. Continuer à avancer ou à retirer le ballonnet alors qu'il existe une résistance peut mobiliser le DSV et/ou causer des lésions tissulaires à la cavité vaginale. Pour s'assurer que le dégonflage total est obtenu, rebrancher la seringue et retirer tout l'air avant de continuer le retrait du ballonnet.

Retrait du DSV

Le DSV est retiré de la patiente une fois qu'une cicatrisation suffisante s'est constituée, c.-à-d. environ 3 à 4 semaines après la chirurgie. Pendant ce temps, les sutures résorbables se seront dissoutes ou auront perdu suffisamment de leurs forces de tension pour permettre un retrait facile du DSV, sans résistance des sutures. **REMARQUE : la section des deux sutures peut être nécessaire pour que le retrait soit possible. REMARQUE : ne pas laisser le DSV à l'intérieur du vagin plus de 4 semaines.** Retirer toute suture d'attache du DSV. Manuellement, retirer le DSV du conduit vaginal comme indiqué sur la figure 19.

Soins péri-opératoires

À titre prophylactique, les patientes reçoivent des antibiotiques. Ces antibiotiques peuvent être poursuivis après la chirurgie en fonction des préférences du chirurgien. Une prophylaxie anti-thrombotique peut être prescrite.

Le chirurgien doit expliquer que l'objectif du DSV, qui demeure dans le vagin jusqu'à quatre semaines au maximum suivant l'opération, est de soutenir le vagin contre la prothèse pendant la période de cicatrisation. La patiente doit être prévenue que le DSV sera retiré lors du contrôle post-opératoire environ 4 semaines après l'opération. La patiente doit être avertie qu'elle risque de subir des écoulements vaginaux post-opératoires et que le DSV peut légèrement se déplacer vers le bas. Si la patiente sent que le DSV s'est déplacé vers le bas, elle peut le repousser doucement vers le haut dans une position plus confortable. Cependant, si le DSV est la source d'une gêne importante, la patiente doit être informée de contacter son médecin.

Après la sortie de l'hôpital, la patiente est invitée à éviter les activités pénibles durant une période de 3 à 4 semaines. Pendant ce temps, les tissus pelviens auront colonisé la prothèse, et la patiente pourra reprendre alors les activités d'une vie normale. Il est conseillé à la patiente d'éviter tout rapport sexuel pendant au moins 6 semaines suivant la chirurgie. Les exercices du plancher pelvien peuvent être recommandés peu de temps après la chirurgie.

MODE D'ACTION

Des études réalisées sur l'animal ont montré que l'implantation du treillis GYNECARE GYNEMESH PS faisait apparaître une réaction inflammatoire minime à légère, qui est transitoire et suivie d'une incorporation progressive du treillis par la fibrose consécutive à la colonisation des mailles du treillis. Le treillis reste souple et flexible et la cicatrisation normale de la plaie n'est pas sensiblement affectée. Le matériau n'est pas résorbé ou dégradé ni fragilisé par l'action des enzymes tissulaires.

CONTRE-INDICATIONS

- Lorsque le treillis GYNECARE GYNEMESH PS est utilisé chez le nourrisson, l'enfant, la femme enceinte ou désirant une grossesse, le chirurgien doit être averti que ce produit n'est pas suffisamment extensible pour accompagner la croissance du patient.
- Les systèmes GYNECARE PROSIMA ne doivent pas être utilisés en cas de grossesse, d'infection purulente ou de cancer du vagin, du col ou de l'utérus.

MISES EN GARDE ET PRÉCAUTIONS

- Avant d'employer les systèmes GYNECARE PROSIMA, l'utilisateur doit connaître les techniques et règles chirurgicales relatives à l'utilisation des treillis non résorbables pour la réparation du plancher pelvien.
- L'utilisation du système GYNECARE PROSIMA n'a pas été complètement évaluée chez les patientes atteintes d'un prolapsus de l'organe pelvien de Stade IV. Ainsi, son utilisation chez ce type de patientes n'est pas recommandée.
- Des pratiques chirurgicales reconnues doivent être suivies lors de l'utilisation du système GYNECARE PROSIMA ainsi que lors de la prise en charge des plaies infectées ou contaminées.
- Ne pas utiliser le système GYNECARE PROSIMA si le site opératoire est susceptible d'être infecté ou contaminé. Dans le cas où la prothèse ou l'ensemble DSV/ballonnet est utilisé dans une région contaminée, le chirurgien doit être conscient que le dispositif pourra être potentiellement retiré en cas d'infection avérée.
- Après l'opération, la patiente doit être avertie qu'elle doit s'abstenir d'éviter de soulever des charges lourdes et/ou de faire de l'exercice (par ex. vélo, jogging) pendant 3 à 4 semaines et d'éviter tout rapport sexuel pendant 6 semaines, ou jusqu'à ce que le médecin l'autorise à reprendre une activité normale.
- Ne pas laisser le DSV à l'intérieur du vagin plus de 4 semaines.
- Ne pas laisser le ballonnet dans le vagin plus d'une journée.
- Les composants du système GYNECARE PROSIMA ne doivent pas être utilisés avec des dispositifs autres que ceux qui sont mentionnés dans cette notice d'emballage.
- Éviter d'appliquer une tension excessive sur la prothèse lors de sa manipulation.
- Utiliser avec précaution les systèmes GYNECARE PROSIMA, en faisant attention à l'anatomie de la patiente, afin d'éviter d'endommager les vaisseaux, les nerfs, la vessie et l'intestin, ainsi que la perforation de la paroi vaginale. L'utilisation correcte des composants du système GYNECARE PROSIMA permettra de minimiser les risques.
- Ne gonfler le ballonnet qu'avec de l'air ambiant.
- Après gonflage du ballonnet, une palpation doit confirmer qu'il n'existe aucune fuite. Un gonflage imparfait du ballonnet en limite l'efficacité.
- La paroi du ballonnet est fine afin de lui conférer les propriétés souhaitées. Les piqûres, coupures, éraflures, écrasements ou suppressions, peuvent être responsables d'une perte de gonflage. Le ballonnet peut être facilement percé par une aiguille, un scalpel ou se rompre lors d'une manipulation avec un instrument peu tranchant. Lors de sa manipulation, une grande attention devra s'exercer pour empêcher de telles éventualités. Un ballonnet endommagé ne doit pas être utilisé. Le retirer et garnir avec de la gaze.
- Le gonflage maximum du ballonnet est de 90 ml. Ne pas le surgonfler. Un gonflage excessif peut gêner la patiente, nécroser les tissus, rompre la cicatrice en post-opératoire ou empêcher la miction.
- Ne pas utiliser les systèmes GYNECARE PROSIMA chez les patientes qui sont sous traitement anti-coagulant.
- Un saignement peut apparaître en post-opératoire. En rechercher tout symptôme ou signe avant de laisser sortir la patiente de l'hôpital.
- La patiente devra être informée de contacter immédiatement le chirurgien en cas de douleur inhabituelle, de saignement ou d'autres problèmes.
- Bien qu'une blessure vésicale soit improbable avec cette technique, une cystoscopie est toutefois recommandée.
- Bien qu'une blessure rectale soit improbable avec cette technique, un toucher rectal est également recommandé.
- Ne pas fixer le treillis GYNECARE GYNEMESH PS avec des agrafes, des clips ou des clamps, car ils pourraient causer des dommages mécaniques au treillis.
- La prothèse ne doit pas se trouver en regard du tiers inférieur du vagin. Si nécessaire, la découper à la hauteur de la jonction tiers inférieur/tiers moyen de la paroi vaginale.
- À titre prophylactique, des antibiotiques peuvent être administrés selon les pratiques usuelles du chirurgien.

EFFETS INDÉSIRABLES

- Les effets indésirables potentiels sont ceux habituellement associés à l'implantation chirurgicale de matériaux incluant une augmentation des risques infectieux, une réaction inflammatoire, la formation d'adhérences, la survenue de fistule ou d'érosion, la possibilité d'extrusion et de cicatrisation entraînant une rétraction de la prothèse.
- Les effets indésirables potentiels sont également ceux généralement observés après la correction des prolapsus des organes pelviens, incluant des rapports sexuels douloureux et des douleurs pelviennes. Ces douleurs peuvent disparaître d'elles-mêmes avec le temps.
- Des piqûres, lésions ou blessures des vaisseaux, nerfs, vessie, urètre ou intestin peuvent se produire lors de la dissection ou lors de la mise en place de la prothèse. Ces blessures peuvent nécessiter une réparation chirurgicale.
- La dissection nécessaire par la réparation du plancher pelvien peut être à l'origine d'une perturbation de la miction sur une durée variable.

STÉRILITÉ

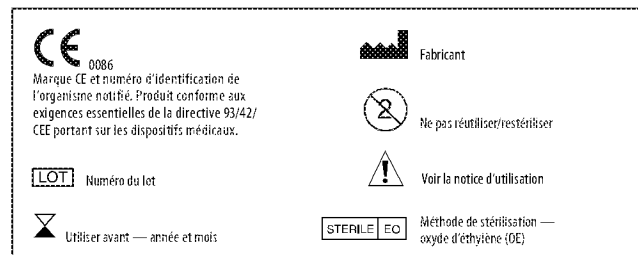
Les systèmes GYNECARE PROSIMA sont stérilisés à l'oxyde d'éthylène. NE RESTÉRILISER aucune partie du système GYNECARE PROSIMA. NE RÉUTILISER aucune partie du système GYNECARE PROSIMA. La réutilisation de ce dispositif (ou de parties de ce dispositif) peut créer un risque de dégradation du produit et une contamination croisée, ce qui peut provoquer une infection ou la transmission d'agents pathogènes transmissibles par le sang aux patients et utilisateurs. Ne pas utiliser un système GYNECARE PROSIMA si son emballage est ouvert ou endommagé. Éliminer tous les composants ouverts et non utilisés du système GYNECARE PROSIMA.

ÉLIMINATION

Éliminer les composants du système GYNECARE PROSIMA et les emballages conformément aux règles et procédures de votre établissement relatives aux matériaux et déchets présentant un danger biologique.

CONSERVATION

Conditions de stockage recommandées : température ambiante et humidité relative contrôlées (environ 25 °C et 60 % d'humidité relative), loin de toute source de chaleur directe et d'humidité. Ne pas utiliser au-delà de la date de péremption.

Symboles utilisés pour l'étiquetage

Gynecare PROSIMA™

Anteriores Beckenboden-Rekonstruktionssystem
Posteriore Beckenboden-Rekonstruktionssystem
Kombiniertes Beckenboden-Rekonstruktionssystem

Bitte alle Informationen sorgfältig lesen.

Eine Nichtbeachtung der Gebrauchsanweisung kann zu einer Fehlfunktion der Instrumente und zu Verletzungen führen.

ACHTUNG: Laut Gesetz ist der Verkauf dieses Produkts in den USA nur auf ärztliche Anordnung gestattet.

Eine Schulung über die Verwendung des GYNECARE PROSIMA™ Beckenboden-Rekonstruktionssystems wird empfohlen und angeboten. Wenden Sie sich an den für Sie zuständigen Außendienstmitarbeiter, um diese Schulung zu vereinbaren.

INDIKATIONEN

Die GYNECARE PROSIMA Beckenboden-Rekonstruktionssysteme, bei denen GYNECARE GYNEMESH™ PS nicht-resorbierbare, weiche PROLENE™ Netzeimplantate eingebracht werden, sind zur Gewebeverstärkung und langfristigen Stabilisierung von Faszienstrukturen des Beckenbodens indiziert, entweder als mechanische Stütze oder als Überbrückungsmaterial für den Fasziendefekt. Die Systeme sorgen für eine Stabilisierung des Vaginalkanals während der Heilungsphase nach einer chirurgischen Rekonstruktion bei einem Prolaps der Vaginalwand mit gleichzeitiger Unterstützung der Position der Netzeimplantate.

BESCHREIBUNG

Jedes GYNECARE PROSIMA Beckenboden-Rekonstruktionssystem (anterior, posterior und kombiniert) besteht aus vorgeschrittenen GYNECARE GYNEMESH PS Netzeimplantaten und Instrumenten zur leichteren Einbringung der Implantate sowie zur postoperativen Stütze (siehe Abbildung 1). Die folgende Tabelle fasst die in jedem System enthaltenen Komponenten zusammen:

BECKENBODEN-REKONSTRUKTIONSSYSTEM	KOMPONENTEN (siehe Abbildung 1)				
	Netzeimplantat im Trägers (A)	Vaginal-Splint mit Luftkissen (B&C)	Anteriore Einführinstrument (D)	Posteriore Einführinstrument (E)	Spritze (F)
Anterior	1	1	1		1
Posterior	1	1		1	1
Kombiniert	2	1	1	1	1

Tabelle 1 – Komponenten des GYNECARE PROSIMA Beckenboden-Rekonstruktionssystems

GYNECARE GYNEMESH PS

GYNECARE GYNEMESH PS ist ein Netz, das aus geflochtenen Fäden aus extrudiertem Polypropylen hergestellt wird und in der Zusammensetzung identisch mit dem PROLENE™ Polypropylen-Nahtmaterial ist (ETHICON, INC.). Berichten zufolge ruft dieses Material bei Verwendung als chirurgisches Nahtmaterial keinerlei Reaktionen hervor, und seine Festigkeit bei klinischer Anwendung bleibt unbeeinträchtigt erhalten. Das Netz bietet hohe Zugkraft und Haltbarkeit, ist chirurgisch vielseitig einsetzbar und ausreichend porös, um das notwendige Einwachsen von Gewebe zu ermöglichen. Blaue PROLENE Einzelstränge wurden eingewebt, um Kontraststreifen im Netz darzustellen. Das Netz besteht aus monofilen Fasern mit reduziertem Durchmesser, die auf besondere Weise zu einem Netz gewebt werden, das ca. 50 Prozent flexibler ist als ein normales PROLENE™ Polypropylen-Netz. Das Netz ist so verknüpft, dass die Fadenverbindungen miteinander verkettet sind, so dass es bidirektional dehnbar ist. Durch diese Struktur kann das Netz in jede gewünschte Form und Größe geschnitten werden, ohne auszufransen. Die bidirektionale Elastizität ermöglicht die Adaptation an verschiedene Belastungssituationen im Körper.

Netzeimplantat

Das Netzeimplantat besteht aus GYNECARE GYNEMESH PS. Die Netzeimplantate sind zur Rekonstruktion anteriorer, posteriorer bzw. apikaler vaginaler Defekte y-förmig zugeschnitten. Siehe Abbildung 2. Das Netzeimplantat hat zwei Halteschlaufen und einen zentralen Körper. Am proximalen Ende befindet sich eine apikale Lasche zur Nahtführung, um eine Verschiebung des Netzeimplantats während des Einbringens der Halteschlaufen zu minimieren. Am distalen Ende befindet sich eine distale Kerbe zur Ausrichtung des Netzeimplantats. An den Halteschlaufen des Netzeimplantats befinden sich vorgeformte Taschen, die die Einbringung mit den Einführinstrumenten ermöglichen. Das Netzeimplantat wird in einem Implantatbehälter aus unbeschichtetem Tyvek™ mit durchsichtiger Kunststoffhülle geliefert, aus dem es einfach entnommen werden kann.

Anteriore Einführinstrument

Das nur zum Einmalgebrauch bestimmte anteriore Einführinstrument erleichtert das Einführen der Netzeimplantat-Halteschlaufen in die zuvor präparierten anterioren Gewebekanaläle. **HINWEIS: Das anteriore Einführinstrument dient nicht zur Präparation von Gewebe.** Das anteriore Einführinstrument ist passend zu den Netzeimplantat-Taschen konstruiert, damit die Halteschlaufen auf beiden Seiten der Patientin in das anteriore Kompartiment eingebracht werden können. Siehe Abbildungen 3 und 4.

Posteriore Einführinstrument

Das nur zum Einmalgebrauch bestimmte posteriore Einführinstrument erleichtert das Einführen der Netzeimplantat-Halteschlaufen in die zuvor präparierten posterioren Gewebekanaläle. **HINWEIS: Das posteriore Einführinstrument dient nicht zur Präparation von Gewebe.** Zur kontrollierten Insertion wird ein Standard-Nadelhalter als Stabilisator am posterioren Einführinstrument befestigt. Das posteriore Einführinstrument ist passend zu den Netzeimplantat-Taschen konstruiert, damit die Halteschlaufen auf beiden Seiten der Patientin in das posteriore Kompartiment eingebracht werden können. Siehe Abbildung 5.

Vaginal-Splint (Vaginal Support Device, VSD)

Der nur für den Einmalgebrauch bestimmte VSD dient zur postoperativen Stütze des Vaginalgewebes nach dem Einbringen des Netzes und dem Nahtverschluss der vaginalen Inzision(en). Das apikale Ende ist der breitere Teil des VSD und hat zuschnürbare Abschnitte. Nach der ersten Größenbestimmung in der Patientin kann die Größe des VSD durch Abschniden

der entsprechenden apikalen Abschnitte an die Anatomie der Patientin angepasst werden. Der VSD verbleibt 3–4 Wochen in den oberen zwei Dritteln der Vagina und wird dann aus der Patientin entfernt. Siehe Abbildung 6.

Luftkissen

Das Luftkissen ist ein Einmalprodukt zum Ersatz eines postoperativen vaginalen Gazeverbandes. Das Luftkissenvolumen ist einstellbar, damit der Vaginalkanal ausgefüllt und die Vaginalwand an das Netzeimplantat gedrückt wird. Das Luftkissen ist bereits an den VSD angebracht. Abbildung 7 zeigt das leere Luftkissen ohne daran befestigten VSD. Das Luftkissen verbleibt bis zu einem Tag in der Patientin.

Spritze

Zum Aufblasen des Luftkissens wird eine 50-ml-Spritze mitgeliefert.

ABSCHNITT 1: VERFAHRENSPRINZIPIEN MIT DEM GYNECARE PROSIMA SYSTEM

Eine Beckenbodenrekonstruktion mit dem GYNECARE PROSIMA System zielt darauf ab, eine anatomische, dauerhafte und standardisierte Rekonstruktion eines Prolapses der Beckenorgane zu erreichen. Je nach Lage des Prolapses und Ermessen des Chirurgen kann die Rekonstruktion anterior bzw. posterior vorgenommen werden. Eine Hysterektomie oder eine Uterusfixation kann mit dem GYNECARE PROSIMA Verfahren kombiniert werden. Falls indiziert, kann bei Verwendung des GYNECARE PROSIMA Systems gleichzeitig eine Dammrekonstruktion oder eine suburethrale Umschlingung zur Behandlung einer stressbedingten Harninkontinenz durchgeführt werden. Es kann eine retropubische oder transobturatorische suburethrale Umschlingung verwendet werden.

Die Prolaps-Rekonstruktion wird durch die Einbringung eines oder zweier der Netzeimplantate über einen vaginalen Zugang erreicht. Am Ende der Operation wird ein VSD mit einem aufblasbaren Luftkissen zur Größenanpassung in die Vagina eingebracht und dort vernäht, um Vagina und Netzeimplantat(e) während des Einwachsens von Gewebe zu unterstützen. Nach dem Aufblasen ersetzt das Luftkissen einen herkömmlichen Gazeverband durch Ausfüllen des vaginalen Hohlraums und Aneinanderdrücken von Netzeimplantat(en) und Vagina. Am Tag nach der Operation wird die Luft aus dem Luftkissen abgelassen und das Luftkissen aus der Vagina entfernt, ohne den VSD zu verschieben. Der VSD bleibt für maximal 4 Wochen nach der Operation in situ, während das Gewebe in das oder die Netzeimplantat(e) einwächst.

ABSCHNITT 2: BEGRÜNDUNG FÜR DAS GYNECARE PROSIMA SYSTEM

Nach einer konventionellen Operation wegen Prolaps der Beckenorgane ist das reparierte Gewebe einem erhöhten intraabdominalen Druck ausgesetzt, wenn die Patientin sich bewegt, hustet, erbricht und bei der Darmentleerung drückt. Diese Erhöhungen des intraabdominalen Drucks können die Heilung der vaginalen Rekonstruktion negativ beeinflussen und zu einem Misserfolg der Operation sowie einem Prolaps-Rezidiv führen. Durch Verstärkung der vaginalen Rekonstruktion mit dem Netzeimplantat und Stütze der Vagina mit dem VSD für 3 bis 4 Wochen nach der Operation dient das GYNECARE PROSIMA System zur Reduzierung der Gefahr eines operativen Misserfolgs und Prolaps-Rezidivs.

Bei der anterioren vaginalen Rekonstruktion soll der Körper des Netzeimplantats spannungsfrei zwischen der Harnblase und den oberen zwei Dritteln der Vagina eingebracht werden und sich auf Höhe des Arcus tendineus fasciae pelvis (ATFP) nach lateral erstrecken. Bei der posterioren vaginalen Rekonstruktion soll der Körper des Netzeimplantats spannungsfrei zwischen Rektum und den oberen zwei Dritteln der Vagina eingebracht werden und lateral über den Levator ani-Muskeln liegen. Der apikale Abschnitt des Netzeimplantats soll bis zum vaginalen Apex reichen. Anterior kann das Netzeimplantat an das prävesikuläre Gewebe oder die Zervix geheftet werden. Posterior kann das Netzeimplantat an das prärektale Gewebe oder die Zervix geheftet werden.

Der VSD stützt das Vaginalgewebe nach der Operation und erleichtert das Andrücken des Vaginalgewebes gegen das Netzeimplantat, bis das Einwachsen von Gewebe beginnt. Das Einwachsen von Gewebe durch das Netzeimplantat findet in den 3 bis 4 Wochen nach der Operation statt. Bei Verwendung des GYNECARE PROSIMA Systems ist keine Präparation außerhalb der Beckenhöhle erforderlich, und die Passage von Nahtmaterial und Instrumenten durch das Foramen obturatorium und Ligamentum sacrospinale werden vermieden, wodurch die Operation einfacher durchzuführen ist.

Hysterektomie

Das Ermessen des Chirurgen und die Bedürfnisse der Patientin bestimmen, ob eine begleitende Hysterektomie erforderlich ist. Wenn eine Hysterektomie durchgeführt wird, wird der Verschluss des blind endenden Peritoneums empfohlen, um den Kontakt des Netzeimplantats mit dem Darm zu vermeiden. Ein „T“-Verschluss der Inzision sollte vermieden werden, da dieser die Gefahr einer Freilegung des Netzes erhöht. Wenn eine vaginale Hysterektomie zusammen mit entweder anteriorer oder posteriorer Rekonstruktion oder beiden durchgeführt wird, sollte die Hysterektomie-Inzision zuerst transversal verschlossen werden; anschließend sollten die Inzisionen für die Rekonstruktion so angelegt werden, dass sie keine Verbindung mit der zuvor verschlossenen Hysterektomie-Inzision haben. Dadurch wird die Entstehung einer „T“-Inzision vermieden.

Uteruserhaltung

Das GYNECARE PROSIMA System eignet sich für Situationen, in denen sich der Chirurg oder die Patientin für eine Uteruserhaltung entscheiden.

Vaginale Inzisionen

Die beim GYNECARE PROSIMA System angewandten vaginalen Inzisionen sind die gleichen wie bei einer routinemäßigen Operation zur vaginalen Rekonstruktion. Die Inzisionen sollten durch die gesamte Dicke der Vaginalwand angelegt werden, um die Gefahr einer Freilegung des Netzes zu verringern.

Einbringung des Netzeimplantats

Die Netzeimplantate werden vom VSD in situ gehalten, bis ein Einwachsen von Gewebe stattfindet. Deshalb ist es nicht nötig, die Halteschlaufen des Netzeimplantats zu fixieren. Der apikale Abschnitt des Netzeimplantats kann mit Nahtmaterial wie etwa 2-0 MONOCRYL™ (Poliglecaprone 25) oder 2-0 Coated VICRYL™ (Polyglactin 910) an die Faszie in der Mittellinie am vaginalen Apex geheftet werden. Das vaginale Epithel sollte nicht an das Netzeimplantat angenäht werden.

Erhaltung der Vagina

Die Entfernung oder Exzision von zu viel vaginalem Epithel sollte vermieden werden. Nach der Operation kann eine gewisse Retraktion des Gewebes auftreten, und die vaginale Kapazität könnte weiter reduziert werden, wenn zu viel vaginales Epithel entfernt wurde.

Drei Stufen vaginaler Unterstützung

Bei der vaginalen Rekonstruktion sind im Allgemeinen 3 Stufen vaginaler Unterstützung möglich. Die Verwendung des GYNECARE PROSIMA Systems bei einer Operation soll Stufe I und II dieser Unterstützung ermöglichen, wie nachstehend beschrieben:

Stufe I – Suspension und Unterstützung (oberes Drittel der Vagina)

Das obere Drittel der Vagina (einschließlich des Hohlraums nach Hysterektomie) und der Uterus werden durch zwei Mechanismen gestützt. Erstens liefern das Parametrium (cardinale und utero-sacrale Ligamente) und Paracolpium-Fasern direkte Unterstützung für den Uterus und die obere Vagina. Diese Fasern wirken wie suspensorische Ligamente und entspringen von der Faszie des M. piriformis, vom sacrospinösen Gelenk und dem lateralen Sacrum, und sie treten im lateralen oberen Drittel der Vagina und an der posterolateralen Seite der Zervix ein. Zweitens sorgt die Levatorplatte, gebildet durch die Fusion der rechten und linken Levator-ani-Muskeln zwischen Rektum und Steißbein, für indirekte Unterstützung von Uterus und oberer Vagina. Ein Prolaps von Uterus und Scheidengewölbe tritt als Folge des Versagens dieser direkten und indirekten Stützmechanismen auf. Dabei ist wahrscheinlich eine Schwäche des muskulären Beckenbodens und der suspensorischen Fasern des Parametriums und oberen Paracolpiums beteiligt. Das Ziel der Prolaps-Operation bei Stufe I ist die Wiederherstellung direkter und indirekter Stützmechanismen. Beim GYNECARE PROSIMA System werden die Netziplantatschläufen dazu verwendet, um bei der anterioren vaginalen Rekonstruktion an jedem M. obturator internus und die darüber liegende parietale Faszie und bei der posterioren Rekonstruktion an die sakrospinösen Ligamente zu drücken. Dies liefert direkte Unterstützung durch Suspension und indirekte Unterstützung durch Schaffung einer breiten Netziplantatsstützfläche für die obere Vagina und den Uterus.

Stufe II – Laterale Befestigung (mittleres Drittel der Vagina)

Die mittlere Vagina ist lateral und direkt durch den Arcus tendineus fasciae pelvis (ATFP) an den Muskeln der seitlichen Beckenwand befestigt. Auf dieser Höhe werden die anterioren und posterioren Vaginalwände zwischen den rechten und linken lateralen Befestigungen gedehnt. Bei Stufe II zielt die Prolaps-Rekonstruktion darauf ab, die laterale mittlere Vagina wieder an den Muskeln der seitlichen Beckenwand zu befestigen. Zentrale Defekte der mittleren Vagina erfordern ebenfalls Unterstützung bei Stufe II. Das GYNECARE PROSIMA System stellt erneut eine laterale Befestigung der Vagina an den Muskeln der seitlichen Beckenwand her und sorgt außerdem für eine zentrale fasziale Verstärkung nach dem Einwachsen von Gewebe.

Stufe III – Fusion (unteres Drittel der Vagina)

HINWEIS: Bei Verwendung des GYNECARE PROSIMA Systems ist keine Präparation in diesem Bereich erforderlich. Bei Stufe III verbindet sich anterior das untere Drittel der Vagina mit der Membrana perinei und der Urethra. Posterior verbindet sich das untere Drittel der Vagina mit der Sehnenplatte des Damms und den Levator-ani-Muskeln. Die Gewebe in diesem Bereich werden ohne Netziplantat rekonstruiert, da dieses nicht für eine Verwendung im unteren Drittel der Vagina vorgesehen ist. Das GYNECARE PROSIMA System ist nicht auf Stufe-III-Unterstützungsdefekte ausgerichtet, wenngleich diese durch begleitende Eingriffe wie etwa eine Dammmast behandelt werden können.

ABSCHNITT 3: GEBRAUCHSANWEISUNG

HINWEIS: Beim Lesen dieses Abschnitts sollten die Abbildungen am Anfang dieses Dokuments zu Rate gezogen werden.

OP-Vorbereitung

Eine Operation mit dem GYNECARE PROSIMA System kann je nach Ermessen des Chirurgen, des Anästhesisten und der Patientin mit Allgemein- oder Regionalanästhesie durchgeführt werden.

Die Patientin sollte in Steinschnittlage gelagert werden, mit leicht über den OP-Tisch hängenden Gesäßbacken und gebeugten Hüften. Nach Ermessen des Chirurgen kann die Blase drainiert werden. Vor dem Aufblasen des Luftkissens ist ein Katheter erforderlich, der jetzt gelegt werden kann.

Verwendung des GYNECARE PROSIMA Systems nach Hysterektomie

Anteriore Vaginalrekonstruktion

Wenn nur eine Verstärkung der anterioren Vaginalwand erforderlich ist, wird nur das anteriore GYNECARE PROSIMA Beckenboden-Rekonstruktionssystem verwendet. Dieses enthält 1 Netziplantat und ein speziell für die Verwendung bei der anterioren Vaginalrekonstruktion entwickeltes anteriores Einführinstrument. Wenn die erforderlichen vaginalen Inzisionen und Präparationen erfolgt sind, werden mit dem anterioren Einführinstrument im anterioren Kompartiment Gewebeknäue für die Einbringung der Netziplantatschläufen hergestellt. **HINWEIS:** Das anteriore Einführinstrument darf nicht zur Präparation von Gewebe verwendet werden.

Anteriore Vaginalpräparation

Das anteriore Vaginalepithel wird von der Blase abpräpariert. Dabei wird die gesamte Dicke der Vaginalwand abpräpariert. Diese Präparation sollte durch subepitheliale Hydro-Präparation erleichtert werden. Eine oberflächliche Präparation der Vaginalwand oder eine Aufteilung der Wand in zwei Schichten ist zu vermeiden. Eine solche Präparation kann zu einer sehr dünnen Vaginalwand führen und auch die Blutversorgung der Wand beeinträchtigen, wodurch die Gefahr einer Freilegung des Netzes erhöht wird. Lateral wird die Präparation zur seitlichen Beckenwand und zur Spina ischialis fortgesetzt.

Anteriore Kanalpräparation und Einbringung des Netziplantats

In dieser Beschreibung wird die Präparation zur Herstellung der Kanäle für die Netziplantatschläufen zuerst auf der rechten und dann auf der linken Seite der Patientin durchgeführt. Diese Kanäle werden hergestellt, um das Netziplantat so einbringen zu können, dass der distale Abschnitt der Schläufen jeweils bündig mit der seitlichen Beckenwand und der parietalen Faszie des Obturator-internus-Muskels liegt. Um diese Schläufen einzubringen, kann die Präparation durch Palpation und Identifikation der Spina ischialis auf beiden Seiten begonnen werden. **HINWEIS:** Diese Präparation kann alternativ mit einer Schere und einer stumpfen „Spreiztechnik“ begonnen werden, wobei die Spitzen der Schere stets anterior von der Spina ischialis bleiben. Nach der ersten Präparation folgt eine behutsame fingerpräparation zur Spina ischialis. Sobald Kontakt zur Spina ischialis besteht, mit dem Zeigefinger anterior und superior von der Spina ischialis Platz schaffen. Siehe Abbildung 9A. Die Richtung dieser Präparation ist senkrecht zur seitlichen Beckenwand und stellt einen Hohlraum von etwa 2 cm Breite und 3 cm Höhe her. An der anterioren Präparation ist keine Präparation auf die sakrospinösen Ligamente beteiligt. Diese Präparation stellt einen Kanal anterior und superior der Spina ischialis und oberhalb von ATFP, Obturator-internus-Muskel und seiner parietalen Faszie her. Die gleiche Präparation auf der linken Seite wiederholen.

Ein Falten des prävesikulären Gewebes ist nicht erforderlich. Wenn eine Faltung durchgeführt wird, dann wird sie jedoch nur am zentralen Teil dieses Gewebes vorgenommen. Dadurch wird vermieden, dass der präparierte Bereich zu eng wird. Das Netziplantat so über das prävesikuläre Gewebe legen, dass die Schlaufentaschen nach oben zeigen. Wenn ein Anheften vorgesehen ist, sollte es zu diesem Zeitpunkt durch Legen einer Naht mit beispielsweise 2-0 MONOCRYL oder 2-0 Coated VICRYL im Apex der Vagina und Durchstechen der apikalen Lasche des Netziplantats

erfolgen. Die Heftnaht kann gleich jetzt oder nach Positionierung der Schläufen fixiert werden. Das Anheften der distalen Rille des Netziplantats ist optional und kann mit Nahtmaterial wie 2-0 MONOCRYL oder 2-0 Coated VICRYL durchgeführt werden.

Die Netziplantatschläufen mit dem anterioren Einführinstrument jeweils in den rechten und linken Kanal einführen, der durch die Präparation anterior und superior der Spina ischialis hergestellt wurde (wie oben beschrieben). **HINWEIS:** Die gebogenen Enden des anterioren Einführinstruments sind in entgegengesetzte Richtungen gedreht und sind mit Pfeilmarkierungen zur Anzeige der Positionierungsrichtung versehen. Die Spitze des anterioren Einführinstruments mit dem Pfeil in Richtung rechte Patientenseite in die Schlaufentasche des Netziplantats (siehe Abbildung 8B) auf der rechten Seite der Patientin einführen. **HINWEIS:** Gegenzug kann dazu beitragen, dass die Tasche auf dem anterioren Einführinstrument bleibt. Das anteriore Einführinstrument in einer vertikalen Position halten, so dass der gebogene Teil des Instruments zur posterioren Vaginalwand zeigt. Das anteriore Einführinstrument wird dann mit der Schlaufe darauf in den zuvor hergestellten Gewebekanal geführt (siehe Abbildung 8C), bis der Handgriff die Labia majora auf der gegenüberliegenden Seite berührt. Dies wird dadurch erreicht, dass der Griffteil des anterioren Einführinstruments nach oben und vertikal positioniert wird, so dass die Führungskante und Tasche zur Spina ischialis zeigen. Aus dieser Position wird der Handgriff dann nach unten in eine fast horizontale Stellung gekippt, während er in Kontakt mit dem kontralateralen Oberschenkel gehalten wird. **HINWEIS:** Das Zurückziehen der Blase mit einem chirurgischen Standardinstrument kann die erste Einbringung in den Kanal erleichtern. Ggf. kann ein Zeigefinger im Kanal verwendet werden, um das anteriore Einführinstrument beim ersten Einbringen gegen die Labia majora auf der kontralateralen Seite zu führen, bevor der Handgriff abgesenkt wird. Durch leichtes Drücken nach oben werden die Schlaufentaschen korrekt positioniert und der apikale Abschnitt des Netziplantats wird an den vaginalen Apex gedrückt. **HINWEIS:** Falls während der Insertion der Schlaufe ein Widerstand spürbar ist, muss vor der Fortsetzung des Verfahrens die Ursache festgestellt werden. Ein weiteres Vorschieben des Einführinstruments unter Widerstand kann zur Beschädigung des Netziplantats oder durch zu weites Einführen zu Schäden an wichtigen Gewebestrukturen führen.

Den Handgriff vor Herausziehen des anterioren Einführinstruments in die vertikale Position zurückkippen und die Schlaufe dabei im Kanal zurücklassen. **HINWEIS:** Erste Schlaufe vollständig einführen. **HINWEIS:** Wenn das anteriore Einführinstrument herausgezogen wird, bevor die Netziplantatschläufe die vorgesehene Stelle erreicht hat, muss die Schlaufe entfernt, neu aufgesetzt und nochmals eingeführt werden. Dieses Verfahren wird auf der anderen Seite der Patientin durch Umdrehen des anterioren Einführinstruments und Einführen des Endes mit dem Pfeil zur linken Patientenseite in die andere Tasche wiederholt. Abbildung 8D zeigt beide eingesetzte Schläufen. **HINWEIS:** Beim Einbringen der zweiten Schlaufe ist ein Verschieben des Netziplantats zu vermeiden und das Implantat darf NICHT verdreht sein.

Der Körper des Netziplantats wird flacher über das darunter liegende Vaginalgewebe gelegt. Ein Falten oder Verdrehen des Körpers und der Schläufen ist zu vermeiden. Je nach vaginalen Abmessungen oder Ausmaß der lateralen Präparation muss der Netziplantatkörper eventuell zugeschnitten werden. Das Vaginalgewebe kann zugeschnitten werden, dabei darf allerdings nicht zu viel Gewebe entfernt werden. Das Epithel wird über dem Netziplantat ohne Verwendung ineinander greifender Nähte verschlossen (wie unten beschrieben, siehe Abbildung 8E). Die endgültige Position des Netziplantats im anterioren Kompartiment ist in Abbildung 8F dargestellt.

HINWEIS: Vor dem Nahtverschluss der vaginalen Inzisionen muss eine Blutstillung hergestellt werden.

Vaginale Inzisionen sollten nicht mit ineinander greifenden oder Achter-Nähten verschlossen werden. Dadurch wird eine Devaskularisierung des Vaginalepithels entlang der Inzisionslinien vermieden und die Erosion des Netzes reduziert. Vorzugsweise wird das Epithel in zwei Schichten vernäht, um eine relativ dicke Knahtlinie an der vaginalen Inzision zu erhalten. Die tiefe Schicht wird mit einer fortlaufenden subepithelialen Matratzennaht mit 2-0 MONOCRYL Nahtmaterial oder 2-0 MONOCRYL™ Plus (Polyglactin 25) antibakteriellem Nahtmaterial verschlossen. Das Epithel wird dann mit einer fortlaufenden umgedrehten Matratzennaht und mit 2-0 Coated VICRYL Nahtmaterial oder 2-0 Coated VICRYL™ Plus (Polyglactin 910) antibakteriellem Nahtmaterial vernäht. **HINWEIS:** Das Netziplantat in den oberen zwei Dritteln der Vagina positionieren und zuschneiden, falls es darüber hinaus reicht. Falls dies nicht bereits erfolgt ist, wird eine Zystoskopie empfohlen, um eine Verletzung des Harntrakts auszuschließen.

Alternativ kann ein einschichtiger Verschluss der Vaginalwand durchgeführt werden. Dabei können eine fortlaufende, umgedrehte Matratzennaht oder Einzelnähte mit 2-0 Coated VICRYL oder 2-0 Coated VICRYL Plus verwendet werden.

Posteriore Vaginal-Rekonstruktion

Wenn nur eine Verstärkung der posterioren Vaginalwand erforderlich ist, wird nur das posteriore GYNECARE PROSIMA Beckenboden-Rekonstruktionssystem verwendet. Dieses enthält ein Netziplantat und ein speziell für die Verwendung bei der posterioren Vaginalrekonstruktion entwickeltes posteriores Einführinstrument. Nach Anlegen der erforderlichen vaginalen Inzisionen und Präparationen Gewebeknäue im posterioren Kompartiment herstellen, in die die Netziplantatschläufen eingebracht werden. **HINWEIS:** Das posteriore Einführinstrument darf nicht zur Präparation von Gewebe verwendet werden.

Posteriore Präparation von Vagina und Kanal

Das posteriore Vaginalepithel wird vom prärektalen Gewebe abpräpariert. Wie bei der anterioren Vaginalwand sollte auch hier die gesamte Dicke der posterioren Vaginalwand abpräpariert werden. Diese Präparation sollte durch subepitheliale Hydro-Präparation erleichtert werden. Die Präparation wird lateral auf beiden Seiten bis zu den Levator-ani-Muskeln auf Höhe der Spina ischialis fortgeführt. Die Präparation geht weiter durch beide rektalen Pfeiler und bis auf, aber nicht durch das Ligamentum sacrospiniosum, wodurch Kanäle für die Einführung der Netziplantatschläufen hergestellt werden. Siehe Abbildung 9A.

Die Behandlung einer vorhandenen Enterozele ist optional, kann aber, falls beabsichtigt, je nach bevorzugter Technik des Chirurgen jetzt durchgeführt werden.

Wenn während der anterioren oder posterioren Präparation die Bauchhöhle eröffnet wird, muss diese vor dem Einbringen des Netziplantats verschlossen werden.

Einbringung des posterioren Netziplantats

Ein Falten des prärektalen Gewebes ist nicht erforderlich. Wenn eine solche Faltung jedoch durchgeführt wird, wird nur der zentrale Teil des prärektalen Gewebes gefaltet. Dadurch wird vermieden, dass der präparierte Bereich zu eng wird. Das Netziplantat so über das prärektale Gewebe legen, dass die Schlaufentaschen nach oben zeigen. Wenn ein Anheften vorgesehen ist, sollte es zu diesem Zeitpunkt durch Legen einer Naht mit 2-0 MONOCRYL Nahtmaterial oder 2-0 Coated VICRYL Nahtmaterial im Apex der Vagina und Durchstechen der apikalen Lasche des Netziplantats erfolgen. Die Heftnaht kann gleich jetzt oder nach Positionierung der Schläufen fixiert werden. Das Anheften der distalen Rille des Netziplantats ist optional und kann mit 2-0 MONOCRYL Nahtmaterial oder 2-0 Coated VICRYL Nahtmaterial durchgeführt werden.

Die Netziplantatschläufen mit dem posterioren Einführinstrument jeweils in den rechten und linken Kanal einführen, der durch die beidseitige Präparation zum Ligamentum sacrospiniosum hergestellt wurde (wie oben beschrieben). Das posteriore Einführinstrument mit einem geraden Nadelhalter greifen, wie in Abbildung 9B dargestellt.

HINWEIS: Die Spitze des Nadelhalters in das gerade, gerillte Ende des posterioren Einführinstruments einführen. Das Netziplantat so ausrichten, dass die Schlaufentaschen nach oben zeigen. Die Spitze des posterioren Einführinstruments in die Schlaufentasche auf der rechten Patientenseite einführen (siehe Abbildung 9B). Das posteriore Einführinstrument wird nun mit der Schlaufe in den zuvor hergestellten Gewebekanal geschoben (siehe Abbildung 9C), wobei der Handgriff des Nadelhalters ausgerichtet wird. Die Schlaufe mit ihrer gesamten Länge in den Kanal schieben, so dass die Basis der Schlaufe an der superioren Grenze der fasziellen Präparation liegt.

HINWEIS: Erste Schlaufe vollständig einführen. Wenn das Einführinstrument herausgezogen wird, bevor die Netziplantatschlaufe die vorgesehene Stelle erreicht hat, muss die Schlaufe entfernt, neu aufgesetzt und nochmals eingeführt werden. HINWEIS: Dabei darf nicht zu tief eingeführt werden, um Schäden an wichtigen Gewebestrukturen zu vermeiden. HINWEIS: Falls während der Insertion der Schlaufe ein Widerstand spürbar ist, muss vor der Fortsetzung des Verfahrens die Ursache festgestellt werden. Ein weiteres Verschieben des Einführinstruments unter Widerstand kann zur Beschädigung des Netziplantats oder durch zu weites Einführen zu Schäden an wichtigen Gewebestrukturen führen. Das posteriore Einführinstrument wird entlang des Insertionspfads zurückgezogen, wobei die Schlaufe im Kanal verbleibt. Die Schlaufen drücken an das Ligamentum sacrospinum, ohne es jedoch zu durchdringen. Nähte keinesfalls in das Lig. sacrospinum legen. Das Verfahren mit der zweiten Schlaufe auf der linken Patientenseite wiederholen. Abbildung 9D zeigt beide eingesetzte Schlaufen.

HINWEIS: Beim Einbringen der zweiten Schlaufe ist ein Verschieben des Netziplantats zu vermeiden und das Implantat darf NICHT verdreht sein.

Der Körper des Netziplantats wird locker über das darunter liegende Vaginalgewebe gelegt. Implantatkörper und Schlaufen dürfen nicht gefaltet oder verdreht werden. Je nach vaginalen Abmessungen oder Ausmaß der lateralen Präparation muss der Netziplantatkörper eventuell zugeschnitten werden. Das Epithel der posterioren Vaginalwand kann zugeschnitten werden, dabei darf allerdings nicht zu viel Gewebe entfernt werden. Das Epithel wird über dem Netziplantat ohne Verwendung ineinander greifender Nähte verschlossen (wie unten beschrieben). Die endgültige Position des Netziplantats im posterioren Kompartiment ist in Abbildung 9E dargestellt.

HINWEIS: Vor dem Nahtverschluss der vaginalen Inzisionen muss eine Blutstillung hergestellt werden.

Vaginale Inzisionen sollten nicht mit ineinander greifenden oder Achter-Nähten verschlossen werden. Dadurch wird eine Devaskularisierung des Vaginalepithels entlang der Inzisionslinien vermieden und die Erosion des Netzes reduziert. Vorzugsweise wird das Epithel in zwei Schichten vernäht, um eine relativ dicke Nahtlinie an der vaginalen Inzision zu erhalten. Die tiefe Schicht wird mit einer fortlaufenden subepithelialen Matratzennaht mit 2-0 MONOCRYL Nahtmaterial oder 2-0 MONOCRYL Plus antibakteriellem Nahtmaterial verschlossen. Das Epithel wird dann mit einer fortlaufenden umgedrehten Matratzennaht und mit 2-0 Coated VICRYL Nahtmaterial oder 2-0 Coated VICRYL Plus Nahtmaterial vernäht. **HINWEIS: Das Netziplantat in den oberen zwei Dritteln der Vagina positionieren und zuschneiden, falls es darüber hinaus reicht.** Am Ende der Operation ist eine digitale rektale Untersuchung erforderlich, um eine rektale Verletzung auszuschließen.

Alternativ kann ein einschichtiger Verschluss der Vaginalwand durchgeführt werden. Dabei können eine fortlaufende, umgedrehte Matratzennaht oder Einzelnähte mit 2-0 Coated VICRYL Nahtmaterial oder 2-0 Coated VICRYL Plus Nahtmaterial verwendet werden.

Kombinierte anteriore und posteriore Vaginal-Rekonstruktion

Wenn sowohl eine anteriore als auch posteriore Vaginalwandverstärkung erforderlich ist, wird das kombinierte GYNECARE PROSIMA Beckenboden-Rekonstruktionssystem verwendet. Dieses enthält zwei identische Netziplantate, eines für die anteriore und das zweite für die posteriore Vaginal-Rekonstruktion. Nur das gebogene anteriore Einführinstrument für eine anteriore und nur das gerade posteriore Instrument für eine posteriore Rekonstruktion verwenden. Die anteriore und posteriore Vaginal-Rekonstruktion wird wie oben beschrieben durchgeführt. Es wird empfohlen, zuerst die anteriore Vaginal-Rekonstruktion vorzunehmen. Die endgültige Position der Netziplantate im anterioren und posterioren Kompartiment ist in Abbildung 10 dargestellt. Am Ende der Operation wird eine Zystoskopie empfohlen, um eine Verletzung des Harntrakts auszuschließen. Eine digitale rektale Untersuchung ist erforderlich, um eine rektale Verletzung auszuschließen.

Verwendung des GYNECARE PROSIMA Systems mit Uteruserhaltung (Hysteropexie)

Wenn der prolabierte Uterus erhalten wird, sollte die apikale Lasche des Netziplantats an der Zervix fixiert werden. Die Fixierung des Netziplantats an der Zervix sollte auf Höhe des pubocervikalen Rings erfolgen, wenn das Implantat während der anterioren oder posterioren Vaginal-Rekonstruktion eingebracht wird.

Wenn der Uterus während einer anterioren Vaginal-Rekonstruktion fixiert wird, wird der pubocervikale Ring während der anterioren Vaginalpräparation freigelegt. Eine 2-0 PROLENE Naht wird fest in der anterioren Seite des pubocervikalen Rings verankert. Diese Naht wird auch durch die apikale Lasche des Netziplantats geführt. Die PROLENE Naht an der Lasche wird geknüpft, wenn die Netziplantatschlaufen gelegt sind. Dies fixiert das Netziplantat an der anterioren Fläche der Zervix auf Höhe des pubocervikalen Rings und sorgt dafür, dass sich das Netziplantat mit der Vagina aufwölbt, wenn der VSD korrekt positioniert ist.

Bei der posterioren Rekonstruktion sollte das Netziplantat an der posterioren Zervix auf Höhe oder oberhalb des pubocervikalen Rings fixiert werden. Die blind endende Ausstülpung kann bei der Belegung des Netziplantats an der Zervix eröffnet werden. Das Peritoneum der Ausbuchtung wird oberhalb dieser Naht verschlossen, um ein Verkleben des Darms mit dem Netziplantat zu vermeiden. Wenn der Chirurg sich entscheidet, die Ausbuchtung nicht zu eröffnen, wird der pubocervikale Ring während der posterioren Vaginalpräparation freigelegt. Eine 2-0 PROLENE Naht wird fest in der posterioren Seite des pubocervikalen Rings verankert. Diese Naht wird auch durch die apikale Lasche des Netziplantats geführt. Die PROLENE Naht an der Lasche wird geknüpft, wenn die Netziplantatschlaufen gelegt sind. Dies fixiert das Netziplantat an der posterioren Fläche der Zervix auf Höhe des pubocervikalen Rings.

Bei Verwendung sowohl für anteriore als auch posteriore Vaginal-Rekonstruktionen sollten die Netziplantate an der anterioren und posterioren Seite der Zervix fixiert werden, wie oben beschrieben (siehe Abbildung 11).

Hygienemaßnahmen

Während der Operation die vaginalen Wunden mit Kochsalzlösung spülen. Das Netziplantat so wenig wie möglich manipulieren und auf einwandfreie Hygiene achten.

Einbringen vom VSD und Luftkissen

Am Ende der Operation wird ein VSD in passender Größe mit befestigtem Luftkissen in die Vagina eingebracht und dort mit Nähten fixiert, um ein Verrutschen zu verhindern. Der VSD hat drei mögliche Größen (klein, mittel und groß) und kann vom Chirurgen wie nachstehend beschrieben an die individuelle Anatomie der Patientin angepasst werden.

VSD Anpassung und Zuschneiden

Der VSD wird mit maximaler Größe geliefert. Die passende Größe durch direkte Anprobe des VSD an der Patientin bestimmen. Hierbei wird der maximal große VSD in die Vagina zwischen dem aufgewölbten Apex und dem Hymenring eingeführt. Zum Einführen in die Vagina den VSD an der breitesten Stelle greifen und entlang der Längsachse falten, wobei der Ballon nach oben zeigt (siehe Abbildung 12). Die breiteste Stelle des VSD wird zuerst eingeführt, so dass die Nahtlöcher direkt oberhalb des Hymenrings liegen. **HINWEIS: Das Luftkissen während der Größenbestimmung**

des VSD nicht abnehmen oder beschädigen. Die richtige Größe ist erreicht, wenn der VSD genau in die oberen zwei Drittel der aufgewölbten Vagina passt und das distale Ende sowie die Nahtöffnungen 1 cm oberhalb des Hymenrings liegen (siehe Abbildung 13).

Wenn die große Größe passt, wird der VSD nicht modifiziert. Wenn die mittlere Größe erforderlich ist, wird der oberste Abschnitt vorsichtig und nur mit den Spitzen einer gebogenen Mayo-Schere abgeschnitten, wobei nur kleine Schnitte erfolgen und so eine glatte Schnittkante erreicht wird. An den beschnittenen Stellen dürfen nur minimale Materialreste verbleiben. **HINWEIS: Es ist wichtig, den VSD sehr sorgfältig anzupassen. Wenn ein VSD einmal zugeschnitten ist, kann er nicht wieder vergrößert und die abgeschnittenen Teile können nicht wieder angesetzt werden.** Das Luftkissen sollte während des Zuschneidens abgehalten werden (siehe Abbildung 14). **Es muss darauf geachtet werden, das Luftkissen beim Zuschneiden des VSD nicht zu beschädigen.**

Wenn die mittlere Größe passt, ist kein weiteres Zuschneiden erforderlich. Wenn die kleine Größe benötigt wird, wird der verbleibende Abschnitt wie oben beschrieben entfernt. Das Luftkissen darf sich während des Zuschneidens nicht im Schneidebereich befinden, um eine Beschädigung zu vermeiden.

Wenn der VSD die korrekte Größe hat und das Luftkissen repositioniert ist, kann die Einheit in die Vagina eingebracht werden. **HINWEIS: Um eine Perforation des Luftkissens zu vermeiden, dürfen zur Einführung des VSD oder des Luftkissens keine Instrumente verwendet werden.** Wenn das Luftkissen beschädigt wird, das Luftkissen vom VSD abnehmen und den Vaginalraum mit Gaze auffüllen.

Nach korrekter Positionierung der Einheit in den oberen zwei Dritteln der aufgewölbten Vagina sollte der VSD mit Einzelnähten durch alle Nahtöffnungen des VSD und in das posteriore Vaginalwandepithel fixiert werden, beidseitig lateral und oberhalb des Hymens in 4- und 8-Uhr-Position, wie in Abbildung 15 dargestellt. Die rechten und linken Nähte werden abwechselnd geknüpft, dabei wird der VSD an seiner Position in der Vagina festgehalten. **HINWEIS: Beim Vernähen des VSD darf das Luftkissen nicht punktiert werden.** Für diese Anwendung wird ein Nahtmaterial wie 2-0 Coated VICRYL oder ein gleichwertiges resorbierbares Nahtmaterial empfohlen.

Aufblasen des Luftkissens

Nach dem Vernähen des VSD wird die mittelgelieferte 50-ml-Spritze durch eine Drehbewegung am Luftkissenventil befestigt. **HINWEIS: Nach Einbringen des VSD ist ein Katheter erforderlich, um eine Harnretention zu vermeiden.** Nach dem Aufblasen mit etwas Raumluft (siehe Abbildung 16) wird die gesamte Länge des Luftkissens mit einem Finger palpiert, um zu gewährleisten, dass sich das Luftkissen entfaltet hat und sich über die gesamte Vagina erstreckt. Nach Bestätigung der Entfaltung den Finger herausnehmen und das Luftkissen weiter aufblasen, bis am Scheideneingang nur noch eine Fingerspitze zwischen Luftkissen und Vaginalwand passt. Während des Aufblasens wird eine Stabilisierung des VSD empfohlen. Das aufgeblasene Luftkissen dient dazu, das Netziplantat an die Vaginalwand zu drücken. Das benötigte Luftvolumen zum Aufblasen des Luftkissens variiert je nach Patientin. **HINWEIS: Das maximale Luftkissen-Aufblasvolumen darf 90 ml nicht übersteigen.** Nach ausreichendem Aufblasen wird die Spritze durch Drehen vom Ventil abgenommen. Der Luftschlauch des Luftkissens muss aus der Vagina herausragen, damit er am Oberschenkel der Patientin befestigt werden kann. Die Kappe muss fest auf das Luftkissenventil aufgesetzt werden, damit das Luftkissen sein vorgesehenes Luftvolumen behält (siehe Abbildung 7). **HINWEIS: Die Kappe nicht zu stark festdrehen.** Ggf. kann das Luftvolumen im Luftkissen später mit einer Standardspritze korrigiert (vergrößert oder verringert) werden. Das Luftkissen kann jederzeit palpiert oder visuell überprüft werden, um zu gewährleisten, dass es ausreichend aufgeblasen ist. **HINWEIS: Wenn sich die Patientin bewegt, passt sich das Luftkissen in der Vagina an und zeigt einen scheinbar höheren oder niedrigeren Innendruck. Das ist normal.**

HINWEIS: Das Luftkissen vor Gebrauch nicht vom VSD lösen.

HINWEIS: Das Luftkissen nicht vor dem Einführen in die Vagina aufblasen.

HINWEIS: Wenn sich die VSD-Nahtöffnungen nach dem Aufblasen des Luftkissens mehr als 1 cm über den Hymenring verschoben haben oder wenn an ihnen eine übermäßige Spannung herrscht, den Druck des Luftkissens verringern und ggf. Position oder Größe des VSD korrigieren.

HINWEIS: Wenn sich im Luftkissen Löcher befinden, ein Leck festgestellt wird oder das Luftkissen nach dem Aufblasen seine Form nicht behält, das Luftkissen NICHT verwenden. Es muss vom VSD abgenommen und vorschriftsgemäß entsorgt werden. Anstelle des Luftkissens einen Standard-Gazeverband verwenden.

HINWEIS: Wenn sich der Luftkissenstecker vom VSD löst, muss er wieder eingedrückt werden.

HINWEIS: Den Luftschlauch des Luftkissens nicht in der Vagina fixieren.

HINWEIS: Den Luftschlauch niemals übermäßig knicken, spannen oder verdrehen, um Beschädigungen zu vermeiden.

HINWEIS: Bei eingesetztem Luftkissen keinen Gazeverband verwenden.

Abnehmen des Luftkissens vom VSD

Mit einer Standardspritze wird das Luftkissen einen Tag nach der Operation vollständig entleert und entfernt, wobei der VSD in situ verbleibt. **HINWEIS: Das Luftkissen nicht länger als einen Tag in der Vagina belassen.**

1) Die Kappe vom Luftkissenventil abnehmen.

2) Eine Standardspritze mit 50 ml (oder größer) am Luftkissenventil befestigen und die gesamte Luft aus dem Luftkissen ziehen (siehe Abbildung 17). Es ist wichtig, das Luftkissen vollständig zu entleeren, bevor versucht wird, es vom VSD abzunehmen. **HINWEIS: Bei einem vollständig entleerten Luftkissen wird der Spritzenkolben von selbst zurückgezogen.**

3) Spritze abnehmen.

4) Das Luftkissen kann dann durch vorsichtiges Ziehen am Luftschlauch in kaudale Richtung in der Nähe des Anslusss Steckers abgenommen werden, während mit einem Finger ein behutsamer Gegenzug auf das distale Ende des VSD ausgeübt wird. Siehe Abbildung 18.

HINWEIS: Das Luftkissen nicht zurückziehen, wenn es nicht vollständig entleert und kein Widerstand zu spüren ist. Falls ein Widerstand spürbar ist, muss vor der Fortsetzung des Verfahrens die Ursache festgestellt werden. Ein weiteres Verschieben oder Zurückziehen des Luftkissens unter Widerstand kann zu einer Verschiebung des VSD bzw. Gewebeträume der Vagina führen. Zur vollständigen Entleerung muss die Spritze nochmals angesetzt und die gesamte Luft entfernt werden, bevor das Luftkissen entfernt wird.

Entfernung des VSD aus der Patientin

Der VSD wird aus der Patientin entfernt, nachdem eine ausreichende Heilung eingetreten ist, etwa 3 bis 4 Wochen nach der Operation. Zu diesem Zeitpunkt haben sich die resorbierbaren Nähte möglicherweise so weit aufgelöst oder ausreichend Spannung verloren, dass der VSD leicht und ohne Widerstand durch Nähte entfernt werden kann. **HINWEIS: Zur Entfernung müssen eventuell beide Nähte aufgeschnitten werden. HINWEIS: Den VSD nicht länger als 4 Wochen in der Vagina belassen.** Jegliche verbleibenden Fixierungsnähte für den VSD entfernen. Den VSD manuell aus dem Vaginalkanal entfernen, wie in Abbildung 19 dargestellt.

Perioperative Versorgung

Eine prophylaktische Verordnung von Antibiotika ist entsprechend der üblichen Verfahrensweise des Chirurgen möglich. Antibiotika können nach Ermessen des Chirurgen postoperativ weiter verabreicht werden. Es kann eine Thromboembolie-Prophylaxe angewandt werden.

Der Chirurg sollte erklären, dass der Verwendungszweck des bis zu vier Wochen nach der Operation in der Patientin verbleibenden VSD ist, die Vagina während der Heilungsperiode in Kontakt mit dem Netzimplantat zu halten. Die Patientin sollte darauf hingewiesen werden, dass der VSD ca. 4 Wochen nach der Operation während einer postoperativen Nachuntersuchung entfernt wird. Weiterhin sollte erwähnt werden, dass es postoperativ zu vaginalem Ausfluss kommen kann und dass sich der VSD leicht nach unten verlagern kann. Wenn die Patientin feststellen sollte, dass der VSD verrutscht ist, kann sie ihn selbst behutsam wieder nach oben in eine angenehmere Position schieben. Falls der VSD allerdings erhebliches Unbehagen bereitet, sollte ärztlicher Rat eingeholt werden.

Die Patientin wird angewiesen, nach der Entlassung aus dem Krankenhaus für einen Zeitraum von 3 bis 4 Wochen anstrengende körperliche Aktivitäten zu vermeiden. Nach dieser Zeit sind die Beckengewebe in das Netzimplantat eingewachsen, und die Patientin kann ihre normalen täglichen Aktivitäten wieder aufnehmen. Die Patientin wird angewiesen, mindestens 6 Wochen nach der Operation auf Geschlechtsverkehr zu verzichten. Eine Beckenbodengymnastik kann jederzeit nach der Operation empfohlen werden.

WIRKUNGSWEISE

Tierversuche haben gezeigt, dass die Implantation von GYNECARE GYNEMESH PS Netz vorübergehend minimale bis leichte entzündliche Reaktionen hervorruft, gefolgt von der Ablagerung einer dünnen, fibrösen Gewebeschicht, welche die Zwischenräume des Geflechts durchdringen kann, wodurch das Netz mit dem anliegenden Gewebe verwächst. Das Netz bleibt weich und formbar, und die normale Wundheilung wird kaum beeinträchtigt. Das Material wird weder resorbiert noch durch Gewebsenzyme abgebaut oder geschwächt.

KONTRAINDIKATIONEN

- Wenn das GYNECARE GYNEMESH PS Netz bei Kleinkindern, Kindern, schwangeren Frauen oder Frauen mit Kinderwunsch verwendet wird, sollte der Arzt bedenken, dass das Netz nicht sehr dehnbar ist und sich dem Wachstum der Patientin nicht anpassen kann.
- Das GYNECARE PROSIMA System sollte nicht bei bestehender Schwangerschaft oder purulenten Infektionen oder Krebserkrankungen von Vagina, Zervix oder Uterus durchgeführt werden.

WARNUNGEN UND VORSICHTSMASSNAHMEN

- Der Chirurg sollte mit den entsprechenden Verfahren und Techniken zur Beckenbodenrekonstruktion mit nicht-resorbierbaren Netzimplantaten vertraut sein, bevor die GYNECARE PROSIMA Systeme eingesetzt werden.
- Für die Verwendung des GYNECARE PROSIMA Systems bei Patientinnen mit einem Grad-IV-Prolaps der Beckenorgane liegen noch keine ausreichenden Daten vor. Die Verwendung bei diesen Patientinnen wird daher nicht empfohlen.
- Beim GYNECARE PROSIMA System sollten anerkannte chirurgische Behandlungsmethoden eingehalten werden, ebenso bei infizierten oder kontaminierten Wunden.
- Das GYNECARE PROSIMA System nicht verwenden, wenn Verdacht auf eine Infektion oder Kontamination des Operationsgebiets besteht. Bei der Verwendung des Netzimplantats oder der VSD-Luftkissen-Einheit in kontaminierten Bereichen sollte stets bedacht werden, dass bei einer nachfolgenden Infektion unter Umständen Implantat oder VSD entfernt werden müssen.
- Postoperativ sollte die Patientin angehalten werden, das Heben schwerer Gegenstände und/oder körperliches Training (z.B. Radfahren, Jogging) für 3 bis 4 Wochen und Geschlechtsverkehr für 6 Wochen zu vermeiden, oder bis zu dem vom Arzt festgelegten Zeitpunkt, ab dem die Patientin ihre normalen Aktivitäten wieder aufnehmen kann.
- Den VSD nicht länger als 4 Wochen in der Vagina belassen.
- Das Luftkissen nicht länger als einen Tag in der Vagina belassen.
- Die Komponenten des GYNECARE PROSIMA Systems sind ausschließlich zur Verwendung mit den in dieser Packungsbeilage angegebenen Instrumenten vorgesehen.
- Übermäßige Zugspannung auf das Netzimplantat während der Handhabung vermeiden.
- Die GYNECARE PROSIMA Systeme mit Sorgfalt und unter Beachtung der Patientenanatomie verwenden, um Schäden an Blutgefäßen, Nerven, Blase und Darm sowie eine Perforation der Vaginalwand zu vermeiden. Die korrekte Anwendung des GYNECARE PROSIMA Systems minimiert diese Risiken.
- Das Luftkissen nur mit Raumluft aufblasen.
- Die Palpation bestätigt, dass das Luftkissen nach dem Aufblasen keine Lecks aufweist. Der vollständige Verlust der eingeblasenen Luft kann die Wirksamkeit des Luftkissens einschränken.
- Die Luftkissenwand ist dünn, damit die gewünschten Eigenschaften erreicht werden. Punktierungen, Schnitte, Kerben, Quetschungen oder Überbelastung können zu einem Verlust der eingeblasenen Luft führen. Das Luftkissen kann leicht durch eine Nadel oder ein Skalpell durchstoßen oder durch Manipulation mit einem stumpfen Instrument zerrissen werden. Bei der Handhabung muss vorsichtig vorgegangen werden, um solche Ereignisse zu vermeiden. Ein beschädigtes Luftkissen darf nicht verwendet werden. Luftkissen entfernen und den Bereich mit Gaze auffüllen.
- Das maximale Aufblasvolumen des Luftkissens beträgt 90 ml. Das Luftkissen nicht zu stark aufblasen. Ein übermäßiges Aufblasen des Luftkissens kann zu Beschwerden der Patientin, Gewebenekrose, postoperativer Ruptur der Vaginalwunde oder Unfähigkeit zur Miktation führen.
- Die GYNECARE PROSIMA Systeme nicht bei Patientinnen anwenden, die sich einer Antikoagulationstherapie unterziehen.
- Es können postoperative Blutungen auftreten. Auf diesbezügliche Symptome oder Anzeichen achten, bevor die Patientin aus dem Krankenhaus entlassen wird.
- Die Patientin muss angewiesen werden, bei Auftreten von ungewöhnlichen Schmerzen, Blutungen oder anderen Problemen sofort den Chirurgen zu benachrichtigen.
- Obwohl eine Verletzung der Blase bei dieser Technik unwahrscheinlich ist, wird empfohlen, eine Zystoskopie durchzuführen.
- Obwohl eine Verletzung des Rektums bei dieser Technik unwahrscheinlich ist, wird empfohlen, eine digitale rektale Untersuchung durchzuführen.
- Das GYNECARE GYNEMESH PS Netzimplantat darf nicht mit irgendwelchen Klammern, Clips oder Klemmen befestigt werden, da es dabei zu einer mechanischen Beschädigung kommen kann.
- Das Netzimplantat darf nicht im unteren Drittel der Vagina liegen. Bei Bedarf das Netzimplantat bis zum Übergang vom unteren zum mittleren Drittel der Vaginalwand zuschneiden.
- Eine prophylaktische Verordnung von Antibiotika ist entsprechend der üblichen Verfahrensweise des Chirurgen möglich.

NEBENWIRKUNGEN

- Zu den möglichen Nebenwirkungen gehören die typischerweise mit chirurgischem Implantatmaterial verbundenen Reaktionen, wie erhöhte Infektionsgefahr, Entzündung, Verwachsungen, Fistelbildung, Erosion, Extrusion und Narbenbildung, die zu einer Kontraktion des Implantats führt.
- Zu den möglichen Nebenwirkungen gehören die typischerweise mit Rekonstruktionsverfahren bei Prolaps von Beckenorganen verbundenen Reaktionen, wie Schmerzen beim Geschlechtsverkehr und Schmerzen im Beckenraum. Diese Beschwerden können mit der Zeit von selbst abklingen.
- Bei der Präparation oder Einbringung des Netzes kann es zu Punktierungen, Zerreißungen oder Beschädigungen von Blutgefäßen, Nerven, Blase, Harnröhre oder Darm kommen, die einer chirurgischen Intervention bedürfen.
- Die Präparation für Beckenboden-Rekonstruktionsverfahren birgt die Gefahr einer Behinderung der normalen Miktation für einen variablen Zeitraum.

STERILITÄT

Die GYNECARE PROSIMA Systeme werden mit Ethylenoxid sterilisiert. KEINE Komponente des GYNECARE PROSIMA Systems darf RESTERILISIERT werden. KEINE Komponente des GYNECARE PROSIMA Systems darf WIEDERVERWENDET werden. Durch Wiederverwendung dieses Produkts (oder von Teilen dieses Produkts) besteht das Risiko einer Produktschädigung oder einer Kreuzkontamination, was zu einer Infektion oder Ansteckung mit durch Blut übertragenen Erregern bei Patienten und Anwendern führen kann. Nicht verwenden, wenn die Verpackung geöffnet oder beschädigt ist. Alle geöffneten, nicht verwendeten GYNECARE PROSIMA Systemkomponenten entsorgen.








ENTSORGUNG

Die Entsorgung von Komponenten und Verpackung des GYNECARE PROSIMA Systems hat unter Beachtung geltender Vorschriften für biogefährliche Stoffe und Abfälle zu erfolgen.

AUFBEWAHRUNG

Empfohlene Lagerbedingungen: kontrollierte Raumtemperatur und relative Luftfeuchtigkeit (ungefähr 25 °C, 60 % relative Luftfeuchtigkeit), geschützt vor Feuchtigkeit und direkter Hitzeeinwirkung. Nicht nach Ablauf des Verfallsdatums verwenden.

Auf den Etiketten verwendete Symbole

		Hersteller
0086 CE-Zeichen und Identifikationsnummer der benannten Stelle. Das Produkt entspricht den grundlegenden Anforderungen der Richtlinie des Rates über Medizinprodukte 93/42/EWG.		Nicht erneut verwenden/resterilisieren
		Gebrauchsanleitung beachten
Chargen-Nr.		Sterilisationsmethode — Ethylenoxid
	Verfallsdatum — Jahr und Monat	



Sistema di riparazione anteriore del pavimento pelvico
Sistema di riparazione posteriore del pavimento pelvico
Sistema di riparazione combinato del pavimento pelvico

Leggere attentamente le istruzioni.

La mancata osservanza di queste istruzioni può causare un funzionamento inadeguato dei dispositivi e provocare lesioni.

ATTENZIONE: la legge federale U.S.A. consente la vendita del prodotto solo dietro richiesta di un medico.

L'addestramento all'uso dei sistemi di riparazione del pavimento pelvico GYNECARE PROSIMA™ è consigliato e disponibile. Per organizzare l'addestramento, contattare il promotore di zona.

INDICAZIONI

I sistemi di riparazione del pavimento pelvico GYNECARE PROSIMA, tramite il posizionamento degli impianti in rete PROLENE™ morbido non assorbibile GYNECARE GYNEMESH™ PS, sono indicati per il rinforzo del tessuto e la stabilizzazione duratura delle strutture fasciali del pavimento pelvico, come supporto meccanico o come materiale di congiunzione per i difetti fasciali. I sistemi assicurano il mantenimento del canale vaginale durante il periodo di guarigione a seguito della riparazione chirurgica del prolasso della parete vaginale, supportando contemporaneamente la posizione degli impianti in rete.

DESCRIZIONE

I sistemi di riparazione anteriore, posteriore e combinato del pavimento pelvico GYNECARE PROSIMA sono formati da impianti in rete GYNECARE GYNEMESH PS pre-sagomati e da strumenti atti a facilitare il posizionamento dell'impianto in rete e il supporto postoperatorio (vedere figura 1). Nella tabella seguente sono elencati i componenti contenuti in ciascun sistema:

SISTEMA DI RIPARAZIONE DEL PAVIMENTO PELVICO	COMPONENTI (vedere figura 1)				
	Impianto in rete nella confezione (A)	Gruppo palloncino – dispositivo di supporto vaginale (B&C)	Introduttore anteriore (D)	Introduttore posteriore (E)	Siringa (F)
Anteriore	1	1	1		1
Posteriore	1	1		1	1
Combinato	2	1	1	1	1

Tabella 1 – Componenti del sistema di riparazione del pavimento pelvico GYNECARE PROSIMA

GYNECARE GYNEMESH PS

GYNECARE GYNEMESH PS è una rete costituita da filamenti intrecciati di polipropilene estruso avente la stessa composizione della sutura in polipropilene PROLENE™ (ETHICON, INC.). Questo materiale, nell'uso come filo di sutura, è risultato non reattivo e, in applicazioni cliniche, ha dimostrato di mantenere la propria resistenza indefinitamente. La rete presenta caratteristiche di resistenza eccellente, durezza e adattabilità come presidio chirurgico, con una porosità sufficiente alla necessaria crescita del tessuto. Nella rete sono stati incorporati dei monofilamenti per sutura blu di PROLENE allo scopo di produrre una rigatura di contrasto. La rete è costituita con fibre monofilamento a diametro ridotto, intrecciate secondo un modello esclusivo che genera una rete di circa il 50 per cento più flessibile delle reti standard in polipropilene PROLENE™. La rete è lavorata con un processo che collega fra di loro le congiunzioni di ogni fibra e che conferisce elasticità in entrambe le direzioni. Questa struttura permette di tagliare la rete in qualunque forma o dimensione desiderata senza che essa si sfili. La proprietà di elasticità bidirezionale consente l'adattamento alle varie tensioni presenti nel corpo.

Impianto in rete

L'impianto in rete è costituito da GYNECARE GYNEMESH PS. Gli impianti in rete sono pre-sagomati a forma di Y per la riparazione di difetti vaginali anteriori, posteriori e/o apicali. Vedere figura 2. L'impianto in rete ha 2 braccia e un corpo centrale. Sull'estremità prossimale vi è una linguetta apicale per il fissaggio con fili di sutura in modo da ridurre al minimo lo spostamento dell'impianto in rete durante il posizionamento delle braccia. Sull'estremità distale vi è una scanalatura per agevolare l'allineamento dell'impianto in rete. In corrispondenza delle braccia dell'impianto in rete ci sono delle tasche pre-moderate per consentire il posizionamento con gli introduttori. L'impianto in rete è fornito in una confezione composta da Tyvek™ non rivestito e da una pellicola in plastica trasparente, pensata per una facile rimozione dell'impianto in rete.

Introduttore anteriore

L'introduttore anteriore è uno strumento per l'utilizzo su una singola paziente, pensato per facilitare l'inserimento delle braccia dell'impianto in rete nei canali anteriori del tessuto precedentemente disseccato. **NOTA: l'introduttore anteriore non è previsto per la dissezione dei tessuti.** L'introduttore anteriore è pensato per essere compatibile con le tasche dell'impianto in rete per consentire il posizionamento delle braccia su entrambi i lati della paziente nel compartimento anteriore. Vedere le figure 3 e 4.

Introduttore posteriore

L'introduttore posteriore è uno strumento per l'utilizzo su una singola paziente, pensato per facilitare l'inserimento delle braccia dell'impianto in rete nei canali posteriori del tessuto precedentemente disseccato. **NOTA: l'introduttore posteriore non è previsto per la dissezione dei tessuti.** Un porta-ago standard si collega all'introduttore posteriore come stabilizzatore per l'inserimento controllato. L'introduttore posteriore è pensato per essere compatibile con le tasche dell'impianto in rete per consentire il posizionamento delle braccia su entrambi i lati della paziente nel compartimento posteriore. Vedere la figura 5.

Dispositivo di supporto vaginale (DSV)

Il DSV è un dispositivo per l'uso su una singola paziente, pensato per fornire un supporto postoperatorio per i tessuti vaginali dopo il posizionamento della rete e dopo la chiusura dell'incisione vaginale. L'estremità apicale è l'estremità più ampia del DSV e contiene sezioni sagomabili. Dopo il dimensionamento iniziale nella paziente, è possibile regolare la dimensione del DSV secondo l'anatomia della paziente rifilando le sezioni apicali sagomabili. Il DSV rimane posizionato nei 2/3 superiori della vagina per 3-4 settimane; dopodiché viene rimosso dalla paziente. Vedere la figura 6.

Palloncino

Il palloncino è un dispositivo per l'uso su una singola paziente, pensato per sostituire il tampone di garza vaginale post-chirurgico. Il volume del palloncino è regolabile in modo da riempire il canale vaginale e arriva fino alla parete vaginale in

corrispondenza dell'impianto in rete. Il palloncino è fornito pre-collegato al DSV. La figura 7 mostra il palloncino sgonfio, senza il DSV collegato. Il palloncino rimane nella paziente al massimo per 1 giorno.

Siringa

Per gonfiare il palloncino viene fornita una siringa da 50 ml.

SEZIONE 1: PRINCIPI DELL'INTERVENTO CON IL SISTEMA GYNECARE PROSIMA

L'intervento di riparazione del pavimento pelvico con il sistema GYNECARE PROSIMA mira ad ottenere una riparazione anatomica, resistente e standardizzata del prolasso dell'organo pelvico. In base alla sede del prolasso e alle preferenze del chirurgo, la riparazione può essere anteriore e/o posteriore. L'isterectomia o la conservazione dell'utero possono essere combinate all'intervento con il sistema GYNECARE PROSIMA. Se indicato, è possibile eseguire una riparazione perineale o posizionare una sling suburetrale per il trattamento dell'incontinenza urinaria da sforzo contemporaneamente all'utilizzo del sistema GYNECARE PROSIMA. È possibile utilizzare una sling suburetrale retropubica o transotturatoria.

La riparazione del prolasso si ottiene con il posizionamento di 1 o 2 impianti in rete per via vaginale. Al termine dell'intervento, un DSV con un palloncino gonfiabile viene posizionato nella vagina per il dimensionamento, quindi il DSV viene suturato in posizione, supportando così la vagina e gli impianti in rete durante la crescita del tessuto. Una volta gonfiato, il palloncino sostituisce il tampone di garza tradizionale riempiendo la cavità vaginale e posizionandosi in corrispondenza degli impianti in rete. Il giorno dopo l'intervento, il palloncino viene sgonfiato e rimosso dalla vagina senza spostare il DSV. Il DSV rimane in posizione per un massimo di 4 settimane dopo l'intervento, durante la crescita del tessuto negli impianti in rete.

SEZIONE 2: RAZIONALE PER IL SISTEMA GYNECARE PROSIMA

Dopo un intervento tradizionale per il prolasso di organo pelvico, i tessuti riparati sono esposti agli aumenti di pressione intra-addominale quando la paziente si muove, tossisce, vomita e compie sforzi con evacuazione intestinale. Questi aumenti di pressione intra-addominale possono compromettere la guarigione della riparazione vaginale e possono portare a fallimenti chirurgici e a prolassi recidivanti. Grazie al rinforzo della riparazione vaginale con l'impianto in rete e al supporto della vagina con il DSV per 3-4 settimane dopo l'intervento, il sistema GYNECARE PROSIMA è pensato per ridurre il rischio di fallimenti chirurgici e prolassi recidivanti.

Durante la riparazione vaginale anteriore, il corpo dell'impianto in rete è previsto che venga posizionato senza tensione tra la vescica e i 2/3 superiori della vagina, estendendosi lateralmente al livello dell'arco tendineo della fascia pelvica (ATFP). Durante la riparazione vaginale posteriore, il corpo dell'impianto in rete è previsto che venga posizionato senza tensione tra il retto e i 2/3 superiori della vagina, sistemandosi lateralmente sui muscoli elevatori dell'ano. È previsto che la sezione apicale del corpo dell'impianto in rete raggiunga l'apice vaginale. Anteriormente, l'impianto in rete può essere fissato al tessuto pre-vescicale o alla cervice. Posteriormente, l'impianto in rete può essere fissato al tessuto pre-rettale o alla cervice.

Il DSV supporta i tessuti vaginali dopo l'intervento e favorisce l'approssimarsi di tali tessuti con l'impianto in rete finché non si verifica la crescita del tessuto. La crescita di tessuto attraverso l'impianto in rete si verifica durante le 3-4 settimane dopo l'intervento. L'utilizzo del sistema GYNECARE PROSIMA evita la necessità di dissezione all'esterno della cavità pelvica ed evita il passaggio di suture e strumenti attraverso il forame otturatorio e il legamento sacrospinoso. Tutti questi aspetti facilitano l'esecuzione dell'intervento stesso.

Isterectomia

Le preferenze del chirurgo e le esigenze della paziente determinano l'eventuale contemporanea necessità di un'isterectomia. Quando si esegue un'isterectomia, si consiglia di eseguire la chiusura del cul-de-sac peritoneale in modo da evitare il contatto dell'impianto in rete con l'intestino. È necessario evitare una chiusura dell'incisione a "T", poiché ciò potrebbe aumentare il rischio di esposizione della rete. Quando si esegue l'isterectomia vaginale insieme alla riparazione anteriore o posteriore o entrambe, prima è necessario chiudere l'incisione dell'isterectomia in senso trasversale, quindi eseguire le incisioni per la riparazione in modo che non si colleghino all'incisione dell'isterectomia precedentemente chiusa. Tale operazione viene eseguita per evitare la creazione di un'incisione a "T".

Conservazione dell'utero

Il sistema GYNECARE PROSIMA è adatto per l'uso in situazioni in cui il chirurgo o la paziente scelgano di conservare l'utero.

Incisioni vaginali

Le incisioni vaginali nell'intervento con il sistema GYNECARE PROSIMA sono uguali a quelle utilizzate dal chirurgo per i tradizionali interventi di riparazione vaginale. Le incisioni devono essere eseguite attraverso tutta la profondità della parete vaginale in modo da ridurre il potenziale rischio di esposizione della rete.

Posizionamento dell'impianto in rete

Gli impianti in rete sono mantenuti in posizione dal DSV finché non si verifica la crescita del tessuto. Pertanto, non è necessario fissare in posizione le braccia dell'impianto in rete. La porzione apicale dell'impianto in rete può essere fissata sulla fascia in corrispondenza della linea mediana dell'apice vaginale usando suture quali MONOCRYL™ 2-0 (Poliglicaprone 25) o Coated VICRYL™ 2-0 (Polyglactin 910). L'epitelio vaginale non deve essere suturato sull'impianto in rete.

Preservazione della vagina

È necessario evitare di rimuovere o escindere troppo epitelio vaginale. In seguito all'intervento può verificarsi una piccola retrazione del tessuto e la capacità vaginale ridotta potrebbe peggiorare se è stato rimosso troppo epitelio vaginale.

Tre livelli di supporto vaginale

Esistono 3 livelli di supporto alla vagina, comunemente conosciuti per la riparazione vaginale. L'utilizzo del sistema GYNECARE PROSIMA in un intervento è previsto per fornire il livello I e II di tale supporto come segue:

Livello I – sospensione e supporto (terzo superiore della vagina)

Il terzo superiore della vagina (compresa la volta in seguito all'isterectomia) e l'utero sono supportati da 2 meccanismi. In prima istanza, il supporto diretto per l'utero e la parte superiore della vagina è fornito dal parametrio (legamenti cardinali e utero-sacrali) e dalle fibre del paracolpo. Tali fibre fungono da legamenti sospensori e nascono dalla fascia

ITALIANO

del muscolo piriforme, dalla giuntura sacroiliaca e dall'osso sacro laterale, e si inseriscono nel terzo superiore laterale della vagina e nella porzione posterolaterale della cervice. Secondariamente, il supporto indiretto per l'utero e la parte superiore della vagina è fornito dalla coppa del muscolo elevatore, formata dalla fusione dei muscoli elevatori dell'ano destro e sinistro tra il retto e il coccige. Il prollasso uterino e della volta vaginale si verificano come conseguenza del cedimento di questi meccanismi di supporto diretto e indiretto. È probabile che tale cedimento coinvolga la debolezza del pavimento pelvico muscolare e delle fibre sospensorie del parametrio e del paracolpo superiore. La chirurgia del prollasso al livello I ha lo scopo di ricreare i meccanismi di supporto diretto e indiretto. Il sistema GYNECARE PROSIMA utilizza le braccia dell'impianto in rete per raggiungere entrambi i muscoli otturatorî interni e le fasce parietali che li ricoprono, nella riparazione vaginale anteriore, e utilizza le braccia dell'impianto in rete per raggiungere i legamenti sacrospinosi nella riparazione vaginale posteriore. Ciò garantisce il supporto diretto tramite sospensione e il supporto indiretto fornendo un'ampia area di supporto dell'impianto in rete per la parte superiore della vagina e per l'utero.

Livello II – fissaggio laterale (terzo medio della vagina)

La parte centrale della vagina è attaccata lateralmente e direttamente ai muscoli sulla parete laterale pelvica tramite l'arco tendineo della fascia pelvica (ATFP). In questo livello, le pareti vaginali anteriore e posteriore sono distese tra i fissaggi laterali destro e sinistro. Al livello II, la riparazione del prollasso punta a fissare di nuovo la porzione medio-laterale della vagina sui muscoli della parete laterale pelvica. I difetti centrali della parte centrale della vagina richiedono anche il supporto al livello II. L'utilizzo del sistema GYNECARE PROSIMA in un intervento ricrea il fissaggio laterale della vagina sui muscoli della parete laterale pelvica e fornisce anche il rinforzo fasciale centrale dopo la crescita del tessuto all'interno della rete.

Livello III – fusione (terzo inferiore della vagina)

NOTA: quando si utilizza il sistema GYNECARE PROSIMA non è richiesta la dissezione in questa area.

Nel livello III, anteriormente il terzo inferiore della vagina si fonde con la membrana perineale e l'uretra. Posteriormente, il terzo inferiore della vagina si fonde con il corpo perineale e i muscoli elevatori dell'ano. I tessuti in questa area sono riparati senza impianto in rete, poiché non è previsto che tale impianto venga utilizzato in corrispondenza del terzo inferiore della vagina. Il sistema GYNECARE PROSIMA non è indicato per i difetti di supporto del livello III, sebbene questi possano essere affrontati con interventi concomitanti come la perineorafia.

SEZIONE 3: ISTRUZIONI PER L'USO

NOTA: quando si legge questa sezione, è necessario fare riferimento alle figure presenti all'inizio di questo documento.

Preparazione chirurgica

L'intervento eseguito con il sistema GYNECARE PROSIMA può essere effettuato in anestesia generale o locale secondo le preferenze del chirurgo, dell'anestesista e della paziente.

La paziente deve essere sistemata in posizione litotomica con le natiche leggermente sporgenti dal tavolo operatorio e le anche flesse. A discrezione del chirurgo, è possibile svuotare la vescica. Prima del gonfiaggio del palloncino è necessario un catetere, che potrà essere inserito in questo punto dell'intervento.

Utilizzo del sistema GYNECARE PROSIMA in interventi post-isterectomia

Riparazione vaginale anteriore

Quando è necessario rinforzare solo la parete vaginale anteriore, occorre utilizzare esclusivamente il sistema di riparazione anteriore del pavimento pelvico GYNECARE PROSIMA. Questo sistema contiene 1 impianto in rete e un introduttore anteriore appositamente studiato per l'utilizzo in una riparazione vaginale anteriore. Dopo aver eseguito le incisioni e le dissezioni vaginali necessarie, si creano dei canali di tessuto nel compartimento anteriore per il posizionamento delle braccia dell'impianto in rete tramite l'introduttore anteriore. **NOTA: l'introduttore anteriore non deve essere utilizzato per la dissezione dei tessuti.**

Dissezione vaginale anteriore

L'epitelio vaginale anteriore viene dissezionato e separato dalla vescica. Dissezionare lo spessore completo della parete vaginale. Questa dissezione deve essere facilitata dall'idrodissezione subepiteliale. Evitare la dissezione superficiale della parete vaginale o la separazione della parete vaginale in 2 strati. Tale dissezione può generare una parete vaginale molto sottile e può compromettere anche l'apporto ematico della parete vaginale, aumentando il rischio di esposizione della rete. Lateralmente, proseguire la dissezione verso la parete laterale pelvica e verso la spina ischiatica.

Dissezione del canale anteriore e posizionamento dell'impianto in rete

Eseguire la dissezione per creare i canali per le braccia dell'impianto in rete prima sul lato destro della paziente, poi su quello sinistro. Questi canali sono creati per posizionare l'impianto in rete in modo che la sezione distale delle braccia rimanga a ridosso della parete laterale pelvica e la fascia parietale del muscolo otturatorio interno. Per posizionare queste braccia, cominciare la dissezione palpando e individuando la spina ischiatica su entrambi i lati. **NOTA: in alternativa, questa dissezione può essere iniziata con forbici usando una tecnica di "spinta e apertura", in modo che la punta delle forbici rimanga sempre anteriore alla spina ischiatica.** Far seguire la dissezione iniziale da una dissezione delicata con le dita verso la spina ischiatica. Una volta che si è entrati in contatto con la spina ischiatica, fare scorrere il dito indice per creare uno spazio anteriore e superiore alla spina ischiatica. Vedere figura 8A. La direzione di questa dissezione è perpendicolare alla parete laterale pelvica e crea uno spazio di circa 2 cm in larghezza e 3 cm in altezza. La dissezione anteriore non prevede la dissezione sui legamenti sacrospinosi. Questa dissezione crea un canale anteriore e superiore alla spina ischiatica e superficiale all'ATFP, al muscolo otturatorio interno e alla relativa fascia parietale. Ripetere la stessa dissezione sul lato sinistro.

Non è necessaria la plicatura del tessuto pre-vescicale. Tuttavia, se si esegue la plicatura, effettuarla solo in corrispondenza della parte centrale di questo tessuto. Ciò evita di rendere troppo stretta l'area dissecata. Porre l'impianto in rete sul tessuto pre-vescicale con le tasche di ciascun braccio rivolte verso l'alto. Se è necessario eseguire il fissaggio, deve essere effettuato in questo punto dell'intervento posizionando suture quali MONOCRYL 2-0 o Coated VICRYL 2-0 in corrispondenza dell'apice della vagina e passando attraverso la linguetta apicale dell'impianto in rete. Il fissaggio può essere legato in questo momento o dopo il posizionamento delle braccia. Il fissaggio della scanalatura distale dell'impianto in rete è opzionale e può essere eseguito con suture quali MONOCRYL 2-0 o Coated VICRYL 2-0.

Utilizzando l'introduttore anteriore, posizionare le braccia dell'impianto in rete in ciascun canale destro e sinistro creato dalla dissezione anteriore e superiore alla spina ischiatica (come sopra descritto). **NOTA: le estremità curve dell'introduttore anteriore sono ruotate in direzioni opposte e, su ogni estremità, vi sono delle frecce che indicano la direzione per il posizionamento.** Con la punta della freccia rivolta verso il lato destro della paziente, inserire la punta dell'introduttore anteriore nella tasca dell'impianto in rete (vedere figura 8B) sul lato destro della paziente. **NOTA: una contro-trazione può aiutare a mantenere la tasca agganciata all'introduttore anteriore.** Tenere l'introduttore anteriore in posizione verticale, in modo che la parte curva dello strumento si trovi contro la parete vaginale posteriore. Direzionare l'introduttore anteriore, con l'estremità inserita all'interno della tasca, nel canale di tessuto precedentemente creato (vedere figura 8C) finché l'impugnatura non è a contatto con le grandi labbra sul lato opposto. Tale operazione è realizzata posizionando la parte dell'impugnatura dell'introduttore anteriore in direzione verticale verso l'alto in modo che il bordo di entrata e la tasca vadano verso la spina ischiatica. Una volta in posizione, inclinare l'impugnatura in basso verso la posizione quasi-orizzontale, mantenendo contemporaneamente l'impugnatura a contatto con la parte laterale della coscia opposta. **NOTA: l'utilizzo di**

uno strumento chirurgico standard per far rientrare la vescica può essere utile per il posizionamento iniziale nel canale. Se lo si desidera, inserire il dito indice nel canale per guidare il posizionamento iniziale dell'introduttore anteriore contro le grandi labbra sul lato opposto, prima di abbassare l'impugnatura. Spingere leggermente verso l'alto in modo da garantire il posizionamento corretto delle tasche delle braccia della rete; la sezione apicale dell'impianto in rete raggiungerà l'apice vaginale. **NOTA: se si avverte resistenza durante l'inserimento delle braccia, determinare la causa prima di procedere. Se si continua a fare avanzare l'introduttore in presenza di resistenza, si possono causare danni all'impianto in rete oppure si può verificare un inserimento eccessivo che può causare danni a strutture anatomiche critiche.**

Per rimuovere l'introduttore anteriore, inclinare indietro l'impugnatura verso la posizione verticale prima dell'estrazione, lasciando il braccio della rete nel canale. **NOTA: inserire completamente il primo braccio. NOTA: se si estrae l'introduttore anteriore prima di rilasciare il braccio dell'impianto in rete nella corretta posizione finale, sarà necessario rimuovere, riagganciare e reinserire il braccio dell'impianto in rete.** Ripetere tale operazione sul lato opposto della paziente premendo l'introduttore anteriore ed inserendo l'estremità, con la freccia puntata verso il lato sinistro della paziente, nell'altra tasca. La figura 8D mostra entrambe le braccia in posizione. **NOTA: durante il posizionamento del secondo braccio, prestare attenzione per evitare lo spostamento dell'impianto in rete e verificare che l'impianto in rete NON sia attorcigliato.**

Posizionare il corpo dell'impianto in rete senza tensione sul tessuto vaginale sottostante. Evitare di piegare o attorcigliare il corpo e le braccia. Il corpo dell'impianto in rete potrebbe richiedere una sgonfiatura in base alle dimensioni vaginali o all'entità della dissezione laterale. L'epitelio vaginale può essere sgonfiato, ma deve essere evitata una rimozione eccessiva. Chiudere l'epitelio sull'impianto in rete evitando la sutura incavagliata (come sotto descritto, vedere figura 8E). La figura 8F mostra il posizionamento finale dell'impianto in rete nel compartimento anteriore.

NOTA: verificare la presenza di un'adeguata emostasi prima e durante la chiusura delle incisioni vaginali.

Chiudere le incisioni vaginali senza suture incavagliate o a figura d'otto. Ciò evita la de-vascularizzazione dell'epitelio vaginale lungo le linee di incisione e riduce l'erosione della rete. Preferibilmente, chiudere l'epitelio in 2 strati per ottenere una linea di sutura relativamente spessa in corrispondenza dell'incisione vaginale. Chiudere lo strato più profondo con sutura subepiteliale in continua, non incavagliata, con una sutura quale MONOCRYL 2-0 o una sutura antibatterica quale MONOCRYL™ Plus 2-0 (Poliglicaprone 25). Quindi chiudere l'epitelio con sutura in continua non incavagliata a materasso ai bordi evertenti, con una sutura quale Coated VICRYL 2-0 o una sutura antibatterica quale Coated VICRYL™ Plus 2-0 (Polyglactin 910). **NOTA: posizionare l'impianto in rete nei 2/3 superiori della vagina, prestando attenzione a sgonfiare l'impianto in rete se supera i 2/3 superiori.** Se non è già stata eseguita la distoscopia, si consiglia tale operazione per escludere lesioni del tratto urinario.

In alternativa, è possibile eseguire una chiusura a strato singolo della parete vaginale. È possibile utilizzare una sutura in continua non incavagliata a materasso ai bordi evertenti, o dei punti di sutura staccati utilizzando suture quali Coated VICRYL 2-0 o Coated VICRYL Plus 2-0.

Riparazione vaginale posteriore

Quando è necessario solamente il rinforzo della parete vaginale posteriore, utilizzare esclusivamente il sistema di riparazione posteriore del pavimento pelvico GYNECARE PROSIMA. Questo contiene 1 impianto in rete e un introduttore posteriore appositamente studiato, utilizzato per la riparazione vaginale posteriore. Dopo aver eseguito le incisioni e le dissezioni vaginali necessarie, creare dei canali di tessuto nel compartimento posteriore per il posizionamento delle braccia dell'impianto in rete. **NOTA: l'introduttore posteriore non deve essere utilizzato per la dissezione dei tessuti.**

Dissezione vaginale posteriore e del canale

Dissezionare e separare l'epitelio vaginale posteriore dal tessuto pre-rettale. Come per la parete vaginale anteriore, è necessario dissezionare tutto lo spessore della parete vaginale posteriore. Questa dissezione deve essere facilitata dall'idrodissezione subepiteliale. Proseguire la dissezione lateralmente su ogni lato verso i muscoli elevatori dell'ano al livello della spina ischiatica. Poi proseguire la dissezione negli spazi parauretrali e su, ma non attraverso, ogni legamento sacrospinoso, creando canali in cui saranno posizionate le braccia dell'impianto in rete. Vedere figura 9A.

Il trattamento dell'enterocele pre-esistente è opzionale, ma, se lo si sceglie, deve essere eseguito in questa fase secondo l'intervento preferito del chirurgo.

Se la cavità peritoneale viene aperta durante la dissezione anteriore o posteriore, è necessario chiuderla prima del posizionamento della rete.

Posizionamento dell'impianto in rete posteriore

Non è necessaria la plicatura del tessuto pre-rettale. Tuttavia, se si esegue la plicatura del tessuto pre-rettale, effettuarla solo in corrispondenza della parte centrale del tessuto pre-rettale. Ciò evita di rendere troppo stretta l'area dissecata. Porre l'impianto in rete sul tessuto pre-rettale con le tasche di ciascun braccio rivolte verso l'alto. Se è necessario eseguire il fissaggio, deve essere effettuato in questo punto dell'intervento posizionando suture quali MONOCRYL 2-0 o Coated VICRYL 2-0 in corrispondenza dell'apice della vagina e passando attraverso la linguetta apicale dell'impianto in rete. Il fissaggio può essere legato in questo momento o dopo il posizionamento delle braccia. Il fissaggio della scanalatura distale dell'impianto in rete è opzionale e può essere eseguito con suture quali MONOCRYL 2-0 o Coated VICRYL 2-0.

Utilizzando l'introduttore posteriore, posizionare le braccia dell'impianto in rete in ciascun canale destro e sinistro creato dalla dissezione verso ciascun legamento sacrospinoso (come sopra descritto). Afferrare l'introduttore posteriore usando un normale porta-aghi, come mostrato nella figura 9B. **NOTA: posizionare la punta del porta-aghi sull'estremità scanalata dell'introduttore posteriore.** Verificare che l'introduttore posteriore collegato sia allineato con l'impugnatura del porta-aghi. Inserire la punta dell'introduttore posteriore nella tasca sul lato destro della paziente (vedere figura 9B). Quindi direzionare l'introduttore posteriore, con l'estremità inserita all'interno della tasca, nel canale di tessuto precedentemente creato (vedere figura 9C) con l'impugnatura del porta-aghi in posizione verticale. Procedere con l'inserimento del braccio della rete per tutta la sua lunghezza nel canale in modo che la base del braccio arrivi al limite superiore della dissezione fasciale. **NOTA: inserire completamente il primo braccio. Se si estrae l'introduttore prima di rilasciare il braccio dell'impianto in rete nella corretta posizione finale, sarà necessario rimuovere, riagganciare e reinserire le braccia dell'impianto in rete. NOTA: prestare attenzione a non inserire troppo in profondità in modo da evitare danni a strutture anatomiche critiche del tessuto. NOTA: se si avverte resistenza durante l'inserimento delle braccia, determinare la causa prima di procedere. Se si continua a fare avanzare l'introduttore in presenza di resistenza, si possono causare danni all'impianto in rete oppure si può verificare un inserimento eccessivo che può causare danni alle strutture anatomiche critiche.** Ritirare l'introduttore posteriore lungo il percorso di inserimento, lasciando il braccio della rete nel canale. Le braccia raggiungono i legamenti sacrospinosi, senza penetrare in essi. Non applicare suture nei legamenti sacrospinosi. Ripetere l'intervento sul lato sinistro della paziente con il secondo braccio. La figura 9D mostra entrambe le braccia in posizione. **NOTA: durante il posizionamento del secondo braccio, prestare attenzione per evitare lo spostamento dell'impianto in rete e verificare che l'impianto in rete NON sia attorcigliato.**

Posizionare il corpo dell'impianto in rete senza tensione sulla fascia vaginale sottostante. Evitare di piegare o attorcigliare il corpo e le braccia dell'impianto in rete. In base alle dimensioni vaginali o alla entità della dissezione laterale, il corpo dell'impianto in rete potrebbe richiedere una sagomatura. L'epitelio della parete vaginale posteriore può essere sagomato, ma deve essere evitata una rimozione eccessiva. Chiudere l'epitelio della parete vaginale posteriore sull'impianto in rete evitando la sutura incavagliata (come sotto descritto). La figura 9E mostra il posizionamento finale dell'impianto in rete nel compartimento posteriore.

NOTA: verificare la presenza di un'adeguata emostasi prima e durante la chiusura delle incisioni vaginali.

Chiudere le incisioni vaginali senza suture incavagliate o a figura d'otto. Ciò evita la de-vascularizzazione dell'epitelio vaginale lungo le linee di incisione e riduce l'erosione della rete. Preferibilmente, chiudere l'epitelio in 2 strati per ottenere una linea di sutura relativamente spessa in corrispondenza dell'incisione vaginale. Chiudere lo strato più profondo con sutura subepiteliale in continua, non incavagliata, con una sutura quale MONOCRYL 2-0 o una sutura antibatterica quale MONOCRYL Plus 2-0. Quindi chiudere l'epitelio con sutura in continua non incavagliata a materasso ai bordi evertenti, con una sutura quale Coated VICRYL 2-0 o Coated VICRYL Plus 2-0. **NOTA: posizionare l'impianto in rete nei 2/3 superiori della vagina, prestando attenzione a sagomare l'impianto in rete se supera i 2/3 superiori.** Al termine dell'intervento, è necessario eseguire un esame rettale digitale per escludere lesioni rettili.

In alternativa, è possibile eseguire una chiusura a strato singolo della parete vaginale. È possibile utilizzare una sutura in continua non incavagliata a materasso ai bordi evertenti, o dei punti di sutura staccati utilizzando suture quali Coated VICRYL 2-0 o Coated VICRYL Plus 2-0.

Riparazione vaginale combinata anteriore e posteriore

Quando è necessario rinforzare la parete vaginale sia anteriore che posteriore, si utilizza il sistema di riparazione combinato del pavimento pelvico GYNECARE PROSIMA. Questo contiene 2 impianti in rete uguali, uno per la riparazione vaginale anteriore e l'altro per la riparazione vaginale posteriore. Per una riparazione anteriore utilizzare solamente l'introduttore anteriore curvo, mentre per una riparazione posteriore utilizzare solamente l'introduttore posteriore dritto. Eseguire le riparazioni vaginali anteriore e posteriore come sopra descritto. Si consiglia di eseguire per prima la riparazione vaginale anteriore. La figura 10 mostra il posizionamento finale degli impianti in rete nei compartimenti anteriore e posteriore. Al termine dell'intervento, si consiglia di eseguire la cistoscopia in modo da escludere lesioni del tratto urinario. È necessario eseguire un esame rettale digitale per escludere lesioni rettili.

Utilizzo del sistema GYNECARE PROSIMA con preservazione uterina (isteropessi)

Se si conserva l'utero prolassato, è necessario fissare la linguetta apicale dell'impianto in rete alla cervice. Il fissaggio dell'impianto in rete sulla cervice deve avere luogo al livello dell'anello pubo-cervicale, quando l'impianto viene posizionato durante la riparazione vaginale anteriore o posteriore.

Quando si conserva l'utero durante una riparazione vaginale anteriore, l'anello pubo-cervicale è esposto durante la dissezione vaginale anteriore. Posizionare saldamente una sutura PROLENE 2-0 nella superficie anteriore dell'anello pubo-cervicale. Questa sutura è posizionata anche attraverso la linguetta apicale dell'impianto in rete. La sutura PROLENE nella linguetta viene legata dopo aver messo in posizione le braccia dell'impianto in rete. Tale operazione fissa l'impianto in rete alla superficie anteriore della cervice al livello dell'anello pubo-cervicale e garantisce che l'impianto in rete si distenda con la vagina quando si posiziona correttamente il DSV.

Nella riparazione posteriore, fissare l'impianto in rete alla cervice posteriore al livello dell'anello pubo-cervicale o sopra esso. È possibile aprire il cul-de-sac durante il fissaggio dell'impianto in rete alla cervice. Chiudere il cul-de-sac peritoneale sopra questa sutura in modo da evitare che l'intestino aderisca all'impianto in rete. Se il chirurgo sceglie di non aprire il cul-de-sac, l'anello pubo-cervicale sarà esposto durante la dissezione vaginale posteriore. Posizionare saldamente una sutura PROLENE 2-0 nella superficie posteriore dell'anello pubo-cervicale. Questa sutura è posizionata anche attraverso la linguetta apicale dell'impianto in rete. La sutura PROLENE viene legata dopo aver messo in posizione le braccia dell'impianto in rete. Tale operazione fissa l'impianto in rete alla superficie posteriore della cervice al livello dell'anello pubo-cervicale.

Quando vengono utilizzati per le riparazioni vaginali sia anteriore che posteriore, gli impianti in rete devono essere fissati alle superfici anteriore e posteriore della cervice, come sopra descritto (vedere figura 11).

Igiene dell'impianto in rete

Durante l'intervento, irrigare le ferite vaginali con soluzione fisiologica. Mantenere la manipolazione dell'impianto in rete al minimo ed assicurarsi che la rete sia sempre in condizioni di igiene.

Posizionamento del DSV e del palloncino

Al termine dell'intervento, posizionare un DSV, con il palloncino collegato, adeguatamente dimensionato nella vagina e suturarla in posizione per evitare che si dislochi. Il DSV ha 3 potenziali dimensioni (piccolo, medio e grande) e può essere personalizzato dal chirurgo in modo da adattarsi alla lunghezza vaginale della paziente come segue.

Adattamento e sagomatura del DSV

Il DSV è fornito nella dimensione più grande. Determinare la dimensione adeguata del DSV per la paziente utilizzando il DSV stesso per valutare la corretta misura nella paziente. Tale operazione si effettua posizionando il DSV nella sua dimensione più grande nella vagina tra l'apice disteso e l'anello imeneale. Per inserire il DSV nella vagina, afferrare il punto più ampio del DSV e piegarlo lungo l'asse longitudinale con il palloncino rivolto verso l'alto (vedere figura 12). Il punto più ampio del DSV viene inserito per primo, in modo che i fori per la sutura siano posizionati appena sopra l'anello imeneale. **NOTA: non rimuovere o danneggiare il palloncino durante il dimensionamento DSV.** La dimensione corretta si ottiene quando il DSV si adatta comodamente nei 2/3 superiori della vagina distesa, con l'estremità distale e gli occhielli per sutura 1 cm sopra l'anello imeneale (vedere figura 13).

Se la dimensione più grande si adatta, il DSV non sarà modificato. Se è necessaria la dimensione media, la maggior parte della sezione superiore sarà rimossa sagomando attentamente, utilizzando solo la punta delle forbici Mayo curve per effettuare piccoli tagli e garantire un bordo tagliato liscio. È necessario prestare attenzione per ridurre al minimo la quantità di materiale rimanente in corrispondenza delle aree tagliate. **NOTA: è importante sistemare il DSV molto attentamente. Una volta tagliato, il DSV non può essere ingrandito e non è possibile riattaccare le sezioni tagliate.** Durante la sagomatura, spostare il palloncino (vedere figura 14). **Durante la sagomatura del DSV, prestare attenzione per evitare danni al palloncino.**

Se la dimensione media si adatta, non è necessaria un'ulteriore sagomatura. Se è necessaria la dimensione piccola, la sezione rimanente sarà rimossa come sopra. Durante la sagomatura, spostare il palloncino per evitare di danneggiarlo.

Una volta dimensionato correttamente il DSV e riposizionato il palloncino, è possibile inserire il gruppo nella vagina della paziente. **NOTA: per ridurre al minimo il rischio di perforazione del palloncino, non utilizzare strumenti per agevolare l'inserimento del DSV o del palloncino.** Se il palloncino si danneggia, rimuoverlo dal DSV e utilizzare un tampone di garza per riempire la cavità vaginale.

Dopo aver posizionato correttamente il gruppo nei 2/3 superiori della vagina distesa della paziente, fissare il DSV in posizione collocando un singolo filo di sutura attraverso ogni occhiello per sutura del DSV e nell'epitelio della parete

vaginale posteriore, lateralmente e sopra l'imenes su ogni lato, come mostrato nella figura 15, nelle posizioni ore 4 e ore 8. Le suture destra e sinistra sono legate in successione, tenendo il DSV saldamente in posizione all'interno della vagina.

NOTA: prestare attenzione a non perforare il palloncino durante la sutura del DSV in posizione. Per questa applicazione si consiglia di utilizzare suture quali Coated VICRYL 2-0 o suture assorbibili equivalenti.

Insufflazione del palloncino

Dopo aver suturato il DSV in posizione, collegare la siringa fornita da 50 ml ruotandola finché si blocca sulla valvola del palloncino. **NOTA: dopo aver posizionato il DSV, è necessario il posizionamento di un catetere per evitare la ritenzione urinaria.** Dopo l'insufflazione con un piccolo volume di aria (vedere figura 16), palpare tutta la lunghezza del palloncino con un dito per verificare che il palloncino si sia spiegato e sia sistemato in tutta l'estensione della vagina. Una volta verificato lo spiegamento, rimuovere il dito e continuare a gonfiare completamente il palloncino fino a quando solamente la punta del dito si adatta comodamente nell'apertura tra il palloncino e la parete vaginale. Si consiglia di stabilizzare il DSV quando ha luogo l'insufflazione. Il palloncino gonfiato serve per mantenere l'impianto in rete in contatto con la parete vaginale. Il volume di aria necessario per gonfiare in modo sufficiente il palloncino varierà da paziente a paziente. **NOTA: il volume massimo di insufflazione del palloncino non deve superare 90 ml.** Dopo un'insufflazione adeguata, staccare la siringa dalla valvola tramite rotazione. Il tubo d'insufflazione del palloncino deve estendersi fuori dalla vagina per essere fissato alla coscia della paziente. È necessario fissare il coperchio alla valvola del palloncino per garantire che il palloncino mantenga il volume previsto di aria (vedere figura 7). **NOTA: non stringere eccessivamente il coperchio.** Se necessario, è possibile regolare il palloncino successivamente, usando una siringa standard per aumentare o diminuire il volume di aria all'interno del palloncino. In qualsiasi momento è possibile palpare il palloncino o ispezionarlo visivamente per verificare che abbia mantenuto un'insufflazione sufficiente. **NOTA: quando la paziente si sposta, il palloncino si sistema nella cavità vaginale e può sembrare che la pressione aumenti o diminuisca. Ciò è normale.**

NOTA: non staccare il palloncino dal DSV prima dell'utilizzo.

NOTA: non gonfiare il palloncino prima della sua inserzione in vagina.

NOTA: dopo l'insufflazione del palloncino, se gli occhielli per sutura del DSV si sono spostati di oltre 1 cm sopra l'anello imeneale oppure se vi è una tensione eccessiva sulle suture agli occhielli, diminuire la pressione sul palloncino e, se necessario, riposizionare e ridimensionare il DSV.

NOTA: se nel palloncino si nota qualche foro, se si rileva una perdita o se il palloncino non riesce a rimanere esteso dopo l'insufflazione, NON utilizzare il palloncino. Esso deve essere rimosso dal DSV e smaltito con i mezzi opportuni. Utilizzare un tampone di garza standard al posto del palloncino.

NOTA: se lo spinotto di collegamento del palloncino si stacca dal DSV, spingerlo di nuovo in posizione.

NOTA: non fissare il tubo di insufflazione del palloncino nella vagina.

NOTA: per evitare danni, non applicare assolutamente forze estreme per piegare, tendere o ruotare il tubo di insufflazione.

NOTA: non applicare tamponi di garza in presenza di un palloncino.

Rimozione del palloncino dal DSV

Con una siringa standard, gonfiare completamente il palloncino e rimuoverlo 1 giorno dopo l'intervento, lasciando il DSV in posizione. **NOTA: non lasciare il palloncino all'interno della vagina per più di 1 giorno.**

1) Rimuovere il coperchio dalla valvola del palloncino.

2) Collegare una siringa standard da 50 ml (o maggiore) alla valvola del palloncino e sgonfiare completamente il palloncino (vedere figura 17). È importante sgonfiare completamente il palloncino prima di tentare di rimuoverlo dal DSV. **NOTA: un palloncino completamente sgonfiato provocherà la retrazione del pistone della siringa dopo la rimozione di tutta l'aria.**

3) Rimuovere la siringa.

4) Separare il palloncino dal DSV e rimuoverlo dalla paziente tirando delicatamente in direzione caudale sul tubo di insufflazione nella posizione accanto allo spinotto di collegamento del palloncino, fornendo contemporaneamente una delicata contro-trazione sull'estremità distale del DSV con un dito. Vedere la figura 18.

NOTA: non estrarre il palloncino a meno che non sia completamente sgonfio e non si avverta alcuna resistenza. Se si avverte resistenza, determinare la causa prima di procedere. Se si continua a far avanzare o a estrarre il palloncino in presenza di resistenza, si provoca lo spostamento del DSV e/o un trauma del tessuto nella cavità vaginale. Per assicurarsi che si sia verificato uno sgonfiamento completo, ricollegare la siringa ed estrarre tutta l'aria prima di continuare la rimozione.

Rimozione del DSV dalla paziente

Rimuovere il DSV dalla paziente circa 3–4 settimane dopo l'intervento, dopo il verificarsi di una guarigione sufficiente. Entro questo periodo le suture assorbibili possono essersi riassorbite o aver perso la forza di trazione sufficiente per consentire la facile rimozione del DSV senza la resistenza delle suture. **NOTA: per la rimozione potrebbe essere necessario tagliare entrambe le suture.** **NOTA: non lasciare il DSV all'interno della vagina per più di 4 settimane.** Rimuovere tutte le rimanenti suture per il fissaggio del DSV. Rimuovere manualmente il DSV dal canale vaginale, come mostrato nella figura 19.

Trattamento perioperatorio

Le pazienti potranno assumere antibiotici come profilassi, somministrati secondo la procedura usuale del chirurgo. L'assunzione di antibiotici può essere continuata dopo l'intervento in base alle preferenze del chirurgo. Può essere effettuata la profilassi tromboembolica.

Il chirurgo è tenuto a spiegare che lo scopo del DSV, destinato a rimanere in vagina per un massimo di quattro settimane dopo l'intervento chirurgico, è quello di supportare la vagina a riobso della rete durante il periodo di cicatrizzazione. La paziente deve essere informata che il DSV sarà rimosso durante una visita di controllo post-operatoria, trascorse circa 4 settimane dall'intervento chirurgico. Inoltre si deve informare la paziente della possibile comparsa di perdite vaginali post-operatorie e che il DSV potrebbe spostarsi leggermente verso il basso. Se la paziente avverte che il DSV si è spostato verso il basso, dovrà delicatamente farlo risalire verso l'alto, fino a raggiungere una posizione più confortevole. Tuttavia, se il DSV è causa di notevole disagio, la paziente dovrà rivolgersi al proprio medico curante.

Dopo la dimissione dall'ospedale, avvisare la paziente di evitare attività che richiedano uno sforzo fisico per un periodo di 3–4 settimane. In questo periodo i tessuti pelvici avranno incorporato l'impianto in rete e la paziente potrà riprendere le attività della vita normale di tutti i giorni. Avvisare inoltre la paziente di evitare rapporti sessuali per almeno 6 settimane dopo l'intervento. Gli esercizi del pavimento pelvico possono essere raccomandati in qualsiasi momento dopo l'intervento.

PRESTAZIONI

Studi su animali hanno dimostrato che l'impianto GYNECARE GYNEMESH PS causa una reazione infiammatoria minima o leggera, solo transitoria e seguita dal deposito di un sottile strato di tessuto fibroso in grado di crescere attraverso gli interstizi della rete,

incorporando quindi la rete stessa nel tessuto adiacente. La rete resta morbida e pieghevole e la normale guarigione della ferita non viene alterata. Il materiale non viene assorbito, né subisce degrado o indebolimento dall'azione degli enzimi tissutali.

CONTROINDICAZIONI

- Quando si utilizza GYNECARE GYNEMESH PS in neonati, bambini, donne in gravidanza o donne che hanno intenzione di avere una futura gravidanza, il chirurgo deve essere consapevole che questo prodotto potrebbe non estendersi sufficientemente per la crescita della paziente.
- Il sistema GYNECARE PROSIMA non deve essere utilizzato in presenza di gravidanza, infezioni purulenti o cancro della vagina, della cervice o dell'utero.

AVVERTENZE E PRECAUZIONI

- Gli utilizzatori devono conoscere molto bene le procedure e le tecniche chirurgiche che riguardano la riparazione del pavimento pelvico e le reti non assorbibili prima di usare i sistemi GYNECARE PROSIMA.
- L'impiego del sistema GYNECARE PROSIMA non è stato valutato completamente nelle pazienti con prolasso pelvico di IV grado. Per questa ragione il suo impiego non è raccomandato in questo tipo di pazienti.
- Attenersi ad una pratica chirurgica riconosciuta per il sistema GYNECARE PROSIMA e per la gestione di ferite infette o contaminate.
- Non utilizzare il sistema GYNECARE PROSIMA se si pensa che il sito chirurgico possa essere infettato o contaminato. Se si utilizza l'impianto in rete o il gruppo DSV-palloncino nelle aree contaminate, tale operazione deve essere realizzata solamente con la consapevolezza che un'infezione successiva può richiedere la sua rimozione.
- Dopo l'intervento, la paziente dovrà essere informata del fatto che dovrà astenersi dal sollevare pesi e/o svolgere esercizio fisico (ad es. ciclismo, corsa) per 3 o 4 settimane e astenersi da rapporti sessuali per 6 settimane o fino a quando il medico non stabilirà che la paziente può tornare alle normali attività.
- Non lasciare il DSV all'interno della vagina per più di 4 settimane.
- Non lasciare il palloncino all'interno della vagina per più di 1 giorno.
- I componenti del sistema GYNECARE PROSIMA non sono pensati per essere utilizzati con dispositivi diversi da quelli indicati nel presente inserto.
- Durante la manipolazione, evitare di esercitare un'eccessiva tensione sull'impianto in rete.
- Utilizzare i sistemi GYNECARE PROSIMA con cura e attenzione per l'anatomia della paziente, allo scopo di evitare danni a vasi, nervi, vescica, intestino e la perforazione della parete vaginale. Il corretto utilizzo dei componenti del sistema GYNECARE PROSIMA ridurrà al minimo i rischi.
- Insufflare il palloncino solo con aria.
- La palpazione confermerà che il palloncino non presenta perdite d'aria dopo l'insufflazione. La perdita completa del gonfiaggio può limitare l'efficacia del palloncino.
- La parete del palloncino è sottile in modo da presentare le proprietà richieste. Perforazioni, tagli, intaccature, schiacciamenti o tensioni eccessive possono causare la perdita di gonfiaggio. Il palloncino può essere facilmente penetrato con un ago o un bisturi oppure rotto tramite manipolazione con uno strumento smusso. È necessario prestare attenzione durante la manipolazione per evitare tali casi. Non utilizzare un palloncino danneggiato. Rimuovere e tamponare con della garza.
- L'insufflazione massima del palloncino è 90 ml. Non gonfiare eccessivamente il palloncino. L'insufflazione eccessiva del palloncino può causare il disagio della paziente, la necrosi del tessuto, la rottura della ferita vaginale postoperatoria o l'impossibilità di vuotare la vescica.
- Non utilizzare i sistemi GYNECARE PROSIMA su pazienti sottoposte a terapia anticoagulante.
- È possibile che si verifichi un'emorragia dopo l'intervento. Prestare attenzione a eventuali sintomi o segni clinici prima di dimettere la paziente dall'ospedale.
- È necessario avvertire la paziente di contattare immediatamente il medico in caso di dolore insolito, sanguinamento o altri problemi correlati.
- Sebbene sia improbabile che si verifichino lesioni della vescica con questa tecnica, si consiglia di eseguire la cistoscopia.
- Sebbene sia improbabile che si verifichino lesioni rettali con questa tecnica, è necessario un esame digitale.
- Per evitare danni meccanici alla rete, non fissare l'impianto in rete GYNECARE GYNEMESH PS con punti metallici, clip o fermagli.
- L'impianto in rete non deve essere presente nel terzo inferiore della vagina. Se necessario, sagomare l'impianto in rete in corrispondenza della congiunzione del terzo inferiore e medio della parete vaginale.
- È possibile somministrare antibiotici come profilassi secondo la procedura usuale del chirurgo.

EFFETTI COLLATERALI

- I potenziali effetti collaterali sono quelli di solito associati ai materiali impiantabili chirurgicamente, compresa una possibilità di infezione, infiammazione, formazione di aderenze, formazione di fistole, erosione, estrusione e cicatrizzazione con conseguente contrazione dell'impianto.
- I potenziali effetti collaterali sono quelli associati solitamente agli interventi di riparazione del prolasso dell'organo pelvico, compresi dolore durante i rapporti sessuali e dolore pelvico. Tali condizioni possono risolversi autonomamente nel tempo.
- Durante la dissezione o il passaggio della rete possono verificarsi perforazioni, lacerazioni o lesioni di vasi, nervi, vescica, uretra o intestino, che potrebbero necessitare di una riparazione chirurgica.
- La dissezione per gli interventi di riparazione del pavimento pelvico presenta il rischio potenziale di compromettere il normale svuotamento della vescica per una lunghezza variabile di tempo.

STERILITÀ

I sistemi GYNECARE PROSIMA sono sterilizzati con ossido di etilene. NON RISTERILIZZARE alcuna parte del sistema GYNECARE PROSIMA. NON RIUTILIZZARE alcuna parte del sistema GYNECARE PROSIMA. Il riutilizzo del dispositivo (o di parti di esso) può creare un rischio di degradazione del prodotto e di contaminazione crociata, che possono causare infezioni o trasmissione di patogeni di origine ematica a pazienti e utilizzatori. Non usare se la confezione è stata aperta o danneggiata. Eliminare tutti i componenti del sistema GYNECARE PROSIMA aperti e non usati.

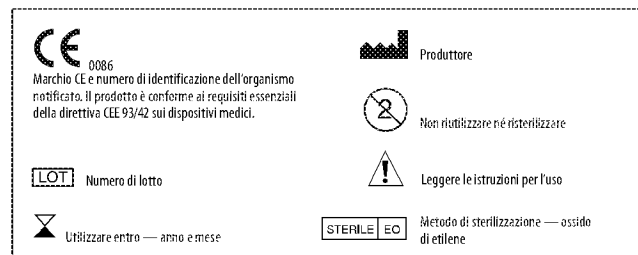
SMALTIMENTO

Smaltire i componenti del sistema GYNECARE PROSIMA e le confezioni conformemente alle politiche dell'azienda e alle procedure relative ai materiali e ai rifiuti a rischio biologico.

CONSERVAZIONE

Condizioni raccomandate per la conservazione: temperatura ambiente e umidità relativa controllate (circa 25 °C, 60 % di umidità relativa), al riparo da umidità e calore diretto. Non usare dopo la data di scadenza.

Simboli usati sulle etichette





Sistema de Reparação do Pavimento Pélvico Anterior
Sistema de Reparação do Pavimento Pélvico Posterior
Sistema de Reparação do Pavimento Pélvico Combinado

Por favor, leia atentamente todas as informações.

O não cumprimento das instruções poderá originar o funcionamento indevido dos dispositivos e provocar lesões pessoais.

ATENÇÃO: A lei federal (dos Estados Unidos da América) só permite a venda deste dispositivo a médicos ou sob receita destes.

Recomenda-se e encontra-se disponível formação relativa ao uso dos Sistemas de Reparação do Pavimento Pélvico GYNECARE PROSIMA™. Contacte o representante de vendas da sua empresa para providenciar esta formação.

INDICAÇÕES

Os Sistemas de Reparação do Pavimento Pélvico GYNECARE PROSIMA, mediante colocação de Implantes de Rede Flexível PROLENE™ Não Absorvível GYNECARE GYNEMESH™ PS estão indicados para reforço do tecido e estabilização de longa duração de estruturas fasciais do pavimento pélvico, como suporte mecânico ou material de ligação para o defeito fascial. Os Sistemas facultam a manutenção do canal vaginal durante o período de cicatrização após reparação cirúrgica do prolapso da parede vaginal, apoiando simultaneamente a posição dos Implantes de Rede.

DESCRIÇÃO

Os Sistemas de Reparação do Pavimento Pélvico Anterior, Posterior e Combinado GYNECARE PROSIMA são constituídos por Implantes de Rede GYNECARE GYNEMESH PS pré-cortados e instrumentos destinados a facilitar a colocação do Implante de Rede e apoio pós-operatório (consultar a figura 1). No quadro seguinte resumem-se os componentes incluídos em cada sistema:

SISTEMA DE REPARAÇÃO DO PAVIMENTO PÉLVICO	COMPONENTES (consultar a figura 1)				
	Implante de Rede na Embalagem de Transporte (A)	Conjunto de Dispositivo de Suporte Vaginal – Balão (B&C)	Introdutor Anterior (D)	Introdutor Posterior (E)	Seringa (F)
Anterior	1	1	1		1
Posterior	1	1		1	1
Combinado	2	1	1	1	1

Quadro 1 – Componentes do Sistema de Reparação do Pavimento Pélvico GYNECARE PROSIMA

GYNECARE GYNEMESH PS

A GYNECARE GYNEMESH PS é uma rede feita a partir de filamentos tecidos de polipropileno extrudido, idêntico em composição à da Sutura de Polipropileno PROLENE™, (ETHICON, INC.). Este material, quando usado como sutura, demonstrou ser não reactivo e manter a sua resistência indefinidamente em uso clínico. A rede dispõe de excelente força, durabilidade e adaptabilidade cirúrgica, com porosidade suficiente para a proliferação interior de tecido necessário. Os monofilamentos azuis da Sutura PROLENE foram introduzidos para criar faixas de contraste na rede. A rede é constituída por fibras monofilamentares de diâmetro reduzido, tecidas de modo a formar um padrão exclusivo que confere a esta rede uma flexibilidade de cerca de 50 por cento superior à da Rede de Polipropileno PROLENE™ standard. A rede é tecida mediante um processo que entrelaça as uniões de cada fibra e que lhe confere elasticidade em ambas as direcções. Este processo de fabrico permite que a rede seja cortada em qualquer formato ou tamanho desejado, sem desfiar. A característica elástica bidireccional permite a adaptação às várias tensões encontradas no corpo.

Implante de Rede

O Implante de Rede é construído a partir de GYNECARE GYNEMESH PS. Os Implantes de Rede são pré-cortados em forma de Y para reparação dos defeitos vaginais anterior, posterior e/ou apical. Consultar a figura 2. O Implante de Rede apresenta 2 tiras e um corpo central. Existe uma aba apical na extremidade proximal para fixação com sutura, visando minimizar os movimentos do Implante de Rede durante a colocação das tiras. Tem um entalhe distal na extremidade distal para ajudar no alinhamento do Implante de Rede. Existem duas bolsas pré-formadas nas tiras do Implante de Rede para permitir a colocação com os introdutores. O Implante de Rede é fornecido numa Embalagem de Transporte do Implante, constituído por Tyvek® não revestido e por uma película de plástico transparente, concebidos para uma fácil remoção do Implante de Rede.

Introdutor Anterior

O Introdutor Anterior consiste num instrumento destinado a ser utilizado numa única doente, concebido para facilitar a inserção das tiras do Implante de Rede nos canais tecidulares anteriores previamente dissecados. **NOTA: O Introdutor Anterior não se destina a ser usado para dissecar tecidos.** O Introdutor Anterior foi concebido para ser compatível com as bolsas do Implante de Rede, visando permitir a colocação de tiras dos dois lados da doente, no compartimento anterior. Consultar a figura 3 e a figura 4.

Introdutor Posterior

O Introdutor Posterior consiste num instrumento destinado a ser utilizado numa única doente, concebido para facilitar a inserção das tiras do Implante de Rede nos canais tecidulares posteriores previamente dissecados. **NOTA: O Introdutor Posterior não se destina a ser usado para dissecar tecidos.** Um porta-agulhas padrão prende-se ao Introdutor Posterior, como estabilizador para uma inserção controlada. O Introdutor Posterior foi concebido para ser compatível com as bolsas do Implante de Rede, visando permitir a colocação de tiras dos dois lados da doente, no compartimento posterior. Consultar a figura 5.

Dispositivo de Suporte Vaginal (VSD)

O VSD é um dispositivo destinado a ser utilizado numa única doente para proporcionar apoio pós-operatório aos tecidos vaginais depois da colocação de rede e encerramento da(s) incisão(ões) vaginal(is). A extremidade apical é a extremidade mais longa do VSD e contém secções recortáveis. Depois do dimensionamento inicial na doente, o tamanho do VSD pode ser ajustado para se adequar à anatomia da doente, cortando as secções apicais indicadas. O VSD fica nos 2/3 superiores da vagina durante 3 a 4 semanas, sendo depois retirado da doente. Consultar a figura 6.

Balão

O Balão é um dispositivo para utilização numa única doente, concebido para substituir o enchimento vaginal por compressas após a cirurgia. O volume do Balão é ajustável, visando encher o canal vaginal e facilitar a aposição da parede vaginal contra o Implante de Rede. O Balão é fornecido pré-fixo ao VSD. Na figura 7 mostra-se o Balão desinflado, sem o VSD. O Balão permanece na doente durante o período máximo de 1 dia.

Seringa

É fornecida uma seringa de 50 ml para insuflar o Balão.

SECÇÃO 1: PRINCÍPIOS DO PROCEDIMENTO UTILIZANDO O SISTEMA GYNECARE PROSIMA

O procedimento de reparação do pavimento pélvico utilizando o Sistema GYNECARE PROSIMA destina-se a obter uma reparação anatómica, durável e padronizada do prolapso dos órgãos pélvicos. Dependendo da localização do prolapso e da preferência do cirurgião, a reparação pode ser anterior e/ou posterior. Pode combinar-se uma histerectomia ou conservação uterina com o procedimento utilizando o Sistema GYNECARE PROSIMA. Caso esteja indicada, pode proceder-se a uma reparação do perineo ou aplicação de faixa (sling) suburetral para tratamento da incontinência urinária de esforço em simultâneo quando se utiliza o Sistema GYNECARE PROSIMA. Pode ser utilizado um sling suburetral retropúbico ou trans-obturador.

A reparação do prolapso é obtida mediante a colocação de 1 ou 2 Implantes de Rede, por abordagem vaginal. Após conclusão da cirurgia, é colocado um VSD com um Balão insuflável na vagina para fins de dimensionamento, sendo o VSD depois suturado, apoiando assim a vagina e o(s) Implante(s) de Rede durante a proliferação tecidual interior. Depois de insuflado, o Balão substitui o enchimento tradicional com compressas, preenchendo a cavidade vaginal e provocando a aposição entre o(s) Implante(s) de Rede e a vagina. No dia a seguir à cirurgia, o Balão é esvaziado e retirado da vagina, sem desalojar o VSD. O VSD permanece colocado durante um período máximo de 4 semanas após a cirurgia, durante a proliferação tecidual interior no(s) Implante(s) de Rede.

SECÇÃO 2: FUNDAMENTOS DO SISTEMA GYNECARE PROSIMA

Após cirurgia convencional para tratamento do prolapso de órgãos pélvicos, os tecidos reparados são expostos a aumentos da pressão intra-abdominal, à medida que a doente se mobiliza, tosse, vomita e faz esforço no momento da evacuação intestinal. Estes aumentos da pressão intra-abdominal podem influenciar negativamente a cicatrização da reparação vaginal e dar origem ao insucesso cirúrgico e recidiva do prolapso. Ao reforçar a reparação vaginal com o Implante de Rede e ao apoiar a vagina com o VSD durante um período de 3 a 4 semanas depois da cirurgia, o Sistema GYNECARE PROSIMA destina-se a reduzir o risco de insucesso cirúrgico e de recidiva do prolapso.

Durante a reparação vaginal anterior, o corpo do Implante de Rede destina-se a ser colocado sem tensão entre a bexiga e os 2/3 superiores da vagina, estendendo-se lateralmente ao nível do arco tendinoso da fáscia pélvica (arcus tendineus fascia pelvis, ATFP). Durante a reparação vaginal posterior o corpo do Implante de Rede destina-se a ser colocado sem tensão entre o recto e os 2/3 superiores da vagina, ajustando-se lateralmente por cima dos músculos elevadores do ânus. A secção apical do corpo do Implante de Rede destina-se a atingir o ápex vaginal. Anteriormente, o Implante de Rede pode ser fixado por meio de sutura ao tecido pré-vescal ou ao colo do útero. Posteriormente, o Implante de Rede pode ser fixado por meio de sutura ao tecido pré-rectal ou ao colo do útero.

O VSD proporciona suporte aos tecidos vaginais após a cirurgia e facilita a aposição dos tecidos vaginais contra o Implante de Rede, até que ocorra a proliferação tecidual interior. A proliferação tecidual interior através do Implante de Rede ocorre durante as 3 a 4 semanas após a cirurgia. A utilização do Sistema GYNECARE PROSIMA evita a necessidade de dissecação fora da cavidade pélvica e evita a passagem de suturas e instrumentos através do foramen do obturador e ligamento sacroespal, facilitando assim a cirurgia.

Histerectomia

A preferência do cirurgião e as necessidades da doente determinam a necessidade de uma histerectomia concomitante. Nas situações em que se efectua histerectomia, recomenda-se o encerramento do peritônio do fundo do saco de Douglas para evitar o contacto do Implante de Rede com o intestino. Deve evitar-se o encerramento de uma incisão em "T", dado que tal pode aumentar o risco de exposição da rede. Quando se efectua histerectomia vaginal em conjunto com a reparação anterior e/ou posterior, a incisão da histerectomia deve ser inicialmente fechada em sentido transversal, procedendo-se depois às incisões de reparação, de tal forma que não comuniquem com a incisão de histerectomia previamente encerrada. Tal destina-se a prevenir a criação de uma incisão em "T".

Conservação Uterina

O Sistema GYNECARE PROSIMA é adequado para utilização em situações em que o cirurgião ou doente optam por conservar o útero.

Incisões vaginais

As incisões vaginais utilizando o Sistema GYNECARE PROSIMA são idênticas às utilizadas pelo cirurgião para cirurgia de reparação vaginal de rotina. As incisões devem ser feitas em toda a profundidade da parede vaginal, de modo a reduzir o potencial de exposição da rede.

Colocação do Implante de Rede

Os Implantes de Rede são mantidos no seu local pelo VSD até que ocorra proliferação tecidual interior. Por conseguinte, é desnecessário fixar as tiras do Implante de Rede em posição. A zona apical do Implante de Rede pode ser fixa com sutura à fáscia na linha média, ao nível do ápex vaginal, utilizando uma sutura como a Sutura MONOCRYL™ 2-0 (Poliglicaprona 25) ou a Sutura Coated VICRYL™ 2-0 (Poliglicactina 910). O epitélio vaginal não deve ser suturado ao Implante de Rede.

Conservação Vaginal

Deve evitar-se remover ou cortar demasiado epitélio vaginal. Após a cirurgia, pode ocorrer algum grau de retração tecidual, podendo existir um agravamento da redução da capacidade vaginal caso se retire demasiado epitélio vaginal.

PORTUGUÊS

Três Níveis de Suporte Vaginal

Conhecem-se tipicamente 3 níveis de suporte vaginal para reparação vaginal. A utilização do Sistema GYNECARE PROSIMA num procedimento destina-se a facultar o nível I e II deste suporte, da seguinte forma:

Nível I – Suspensão e Suporte (terço superior da vagina)

O terço superior da vagina (incluindo a abóbada após histerectomia) e útero é suportado por 2 mecanismos. Em primeiro lugar, o suporte directo do útero e zona superior da vagina é assegurado pelo paramétrio (ligamentos cardial e útero-sagrado) e fibras do paracólio. Estas fibras actuam como ligamentos suspensores e nascem da fáscia do músculo piriforme, articulação sacro-ilíaca e zona lateral do sacro, inserindo-se no terço superior externo da vagina e face póstero-externa do colo do útero. Em segundo lugar, o suporte indirecto do útero e zona superior da vagina é assegurado pela placa elevadora, formada pela fusão dos músculos elevadores do ânus direito e esquerdo, entre o recto e o cóccix. O prolapso do útero e abóbada vaginal ocorre em consequência da falência destes mecanismos de suporte directo e indirecto. É provável que tal envolva a fraqueza do pavimento pélvico muscular e das fibras suspensoras do paramétrio e paracólio superior. O objectivo da cirurgia do prolapso de nível I consiste em recriar mecanismos de suporte directo e indirecto. O Sistema GYNECARE PROSIMA utiliza as tiras do Implante de Rede para aposição a cada músculo obturador interno e fáscia parietal sobrejacente na reparação vaginal anterior e utiliza as tiras do Implante de Rede para aposição aos ligamentos sacrospinais na reparação vaginal posterior. Tal confere suporte directo mediante suspensão e suporte indirecto ao proporcionar uma área ampla de suporte do Implante de Rede para o útero e a zona superior da vagina.

Nível II – Fixação Lateral (terço médio da vagina)

A zona média da vagina é fixa lateral e directamente aos músculos da parede pélvica lateral através do arco tendinoso da fáscia pélvica (ATFP). A este nível, as paredes vaginais anterior e posterior são esticadas entre as fixações laterais direita e esquerda. No nível II, a reparação do prolapso tem por objectivo refixar a linha média lateral da vagina aos músculos da parede pélvica lateral. Defeitos centrais da linha média da vagina também requerem suporte de nível II. A utilização do Sistema GYNECARE PROSIMA num procedimento recia a fixação lateral da vagina aos músculos da parede pélvica lateral e também proporciona um reforço fascial central após a proliferação tecidual interior.

Nível III – Fusão (terço inferior da vagina)

NOTA: Quando se utiliza o Sistema GYNECARE PROSIMA não é necessária dissecação nesta área.

No nível III, o terço inferior da vagina funde-se anteriormente com a membrana perineal e a uretra. Posteriormente, o terço inferior da vagina funde-se com o corpo penial e os músculos elevadores do ânus. Os tecidos desta área são reparados sem o Implante de Rede, dado que o Implante de Rede não se destina a ser usado no terço inferior da vagina. O Sistema GYNECARE PROSIMA não aborda defeitos de suporte de nível III, embora estes possam ser abordados por procedimentos concomitantes, tais como a perineorrafia.

SECÇÃO 3: INSTRUÇÕES DE UTILIZAÇÃO

NOTA: Durante a leitura desta secção, devem consultar-se as imagens facultadas no início deste documento.

Preparação Cirúrgica

A cirurgia efectuada com o Sistema GYNECARE PROSIMA pode ser realizada com anestesia geral ou regional, consoante a preferência do cirurgião, anestesta e doente.

A doente deverá ser colocada na posição de litotomia, com as nádegas higienamente suspensas acima da mesa operatória e as ancas flexidas. O cirurgião pode optar por proceder ao esvaziamento da bexiga. É necessária uma algália antes da insuflação do balão, que pode ser inserida neste momento do procedimento.

Utilização do Sistema GYNECARE PROSIMA em Procedimentos Pós-Histerectomia

Reparação Vaginal Anterior

Quando é apenas necessário reforço da parede vaginal anterior, deve utilizar-se somente o Sistema de Reparação do Pavimento Pélvico Anterior GYNECARE PROSIMA. Este contém 1 Implante de Rede e um Introdutor Anterior concebido especialmente para ser utilizado numa reparação vaginal anterior. Depois de efectuadas as disseções e incisões vaginais necessárias, são criados canais teciduais no compartimento anterior para colocação das tiras do Implante de Rede utilizando o Introdutor Anterior. **NOTA: O Introdutor Anterior não deve ser usado para dissecar tecidos.**

Dissecção Vaginal Anterior

O epitélio vaginal anterior é dissecado da bexiga. Dissecte a parede vaginal em toda a espessura. Esta dissecação deve ser facilitada por hidrodissecção subepitelial. Deve evitar-se a dissecação superficial da parede vaginal ou a separação da parede vaginal em 2 camadas. Esta dissecação pode originar uma parede vaginal muito fina e também comprometer a irrigação sanguínea da mesma, aumentando o risco de exposição da rede. Externamente, prossiga a dissecação em direcção à parede pélvica lateral e à espinha isquiatca.

Dissecção do Canal Anterior e Colocação do Implante de Rede

Para os fins desta descrição, efectue a dissecação destinada a criar canais para as tiras do Implante de Rede primeiro do lado direito da doente e depois do lado esquerdo. Estes canais são criados visando colocar o Implante de Rede de forma a que a secção distal das tiras assente contra a parede pélvica lateral e fáscia parietal do músculo obturador interno. Para colocar estas tiras, inicie a dissecação palpando e identificando a espinha isquiatca dos dois lados. **NOTA: Em alternativa, esta dissecação pode ser iniciada com uma tesoura, utilizando uma técnica de “empurrar-espalhar”, de forma a que as pontas da tesoura permaneçam sempre em posição anterior à espinha isquiatca.** Após a dissecação inicial, efectue uma dissecação suave com o dedo até à espinha isquiatca. Depois de estabelecido o contacto com a espinha isquiatca, “vaza” com o dedo indicador para criar um espaço anterior e superior à espinha isquiatca. Consulte a figura 8A. A direcção desta dissecação é perpendicular à parede pélvica lateral e cria um espaço com aproximadamente 2 cm de largura e 3 cm de altura. A dissecação anterior não envolve dissecação dos ligamentos sacrospinais. Esta dissecação cria um canal anterior e superior à espinha isquiatca e superficial ao ATFP, músculo obturador interno e sua fáscia parietal. Repete a mesma dissecação no lado esquerdo.

Não é necessária plicação do tecido pré-vesical. Todavia, se for feita plicação, só é plicada a zona central deste tecido. Tal evita que a área dissecada se torne demasiado estreita. Coloque o Implante de Rede por cima do tecido pré-vesical, com as bolsas das tiras viradas para cima. Caso se pretenda fixar com sutura, tal deve ser feito neste momento do procedimento colocando uma sutura tal como a Sutura MONOCRYL 2-0 ou a Sutura Coated VICRYL 2-0 no ápex da vagina e enfiando-a através da aba apical do Implante de Rede. A sutura pode ser atada neste momento ou depois de colocadas as tiras. A fixação do entalhe distal do Implante de Rede é opcional e pode ser feita com uma sutura como a Sutura MONOCRYL 2-0 ou a Sutura Coated VICRYL 2-0.

Utilizando o Introdutor Anterior, coloque as tiras do Implante de Rede em cada um dos canais direito e esquerdo criados pela dissecação anterior e superior até à espinha isquiatca (conforme descrito acima). **NOTA: As extremidades curvadas do Introdutor Anterior são torcidas em direcções opostas e existem setas em cada extremidade indicando a direcção para a colocação.** Com a seta a apontar para o lado direito da doente, introduza a ponta do Introdutor Anterior na bolsa para tiras do Implante de Rede (consultar a figura 8B) no lado direito da doente. **NOTA: Uma contra-tracção pode ajudar a manter a bolsa carregada no Introdutor Anterior.** Mantenha o Introdutor Anterior em posição vertical, de tal forma que a parte curva do instrumento fique contra a parede vaginal posterior. Direcione depois o

Introdutor Anterior, com a tira carregada, para o canal tecidual previamente criado (consultar a figura 8C) até que a pega entre em contacto com os grandes lábios, no lado contra-lateral. Tal obtém-se posicionando a zona da pega do Introdutor Anterior em sentido ascendente-vertical, de tal forma que a extremidade dianteira e bolsa se dirijam à espinha isquiatca. Depois de posicionada, incline a pega para baixo, para uma posição praticamente horizontal, mantendo a pega em contacto com a coxa contra-lateral. **NOTA: A retração cirúrgica padrão pode ser útil para a colocação inicial no canal. Se pretender, utilize o dedo indicador no canal para orientar a colocação inicial do Introdutor Anterior contra os grandes lábios no lado contra-lateral, antes de baixar a pega.** Empurrar ligeiramente em sentido ascendente garante que as bolsas das tiras ficam posicionadas adequadamente e que a secção apical do Implante de Rede irá ficar assente contra o ápex vaginal. **NOTA: Se for encontrada resistência durante a inserção das tiras, determine a causa da resistência antes de prosseguir. Continuar a avançar o Introdutor contra resistência pode provocar danos no Implante de Rede ou uma inserção excessiva, provocando lesões em estruturas teciduais críticas.**

Para remover o Introdutor Anterior, incline a pega novamente para a posição vertical antes de retirar, deixando a tira no canal. **NOTA: Insira completamente a primeira tira. NOTA: Se o Introdutor Anterior for puxado e retirado antes de a tira do Implante de Rede chegar ao local pretendido, será necessário remover a tira, voltar a carregá-la e a inseri-la.** Repita no lado oposto da doente virando o Introdutor Anterior e inserindo a extremidade, com a seta a apontar para o lado esquerdo da doente, na outra bolsa. Na figura 8D mostram-se as duas tiras colocadas. **NOTA: Durante a colocação da segunda tira, tome precaução para evitar o movimento do Implante de Rede e confirme que o Implante de Rede NÃO ESTÁ torcido.**

Posicione o corpo do Implante de Rede livremente por cima do tecido vaginal subjacente. Deve evitar-se dobrar ou torcer o corpo e as tiras. Pode ser necessário cortar o corpo do Implante de Rede, dependendo das dimensões vaginais ou da quantidade de dissecação lateral. O epitélio vaginal pode ser cortado, mas deve evitar-se uma remoção excessiva de epitélio vaginal. Encerre o epitélio por cima do Implante de Rede, sem a utilização de suturas de travamento (conforme descrito em 8F, consultar a figura 8E). A colocação final do Implante de Rede no compartimento anterior é mostrada na figura 8F.

NOTA: Assegure-se de que é obtida hemostase antes e durante o encerramento das incisões vaginais.

Encerre as incisões vaginais sem suturas de travamento ou “em oito”, para evitar a desvascularização do epitélio vaginal ao longo das linhas de incisão e reduzir a erosão da rede. Preferivelmente, o epitélio é encerrado em 2 planos para se obter uma linha de sutura relativamente grossa no local da incisão vaginal. Encerre a camada mais profunda utilizando um ponto sem travamento subepitelial contínuo com uma sutura como a Sutura MONOCRYL 2-0 ou a Sutura Antibacteriana MONOCRYL™ Plus (Poliglecaprona 25). De seguida, encerre o epitélio utilizando um ponto de colchoeiro evitado contínuo sem travamento, utilizando uma sutura como a Sutura Coated VICRYL 2-0 ou a Sutura Antibacteriana VICRYL™ Plus (Poliglicatina 910). **NOTA: Coloque o Implante de Rede nos 2/3 superiores da vagina, tomando precaução para cortar o Implante de Rede se este ultrapassar os 2/3 superiores.** Se ainda não tiver sido efectuada, recomenda-se uma cistoscopia para excluir a lesão do aparelho urinário.

Em alternativa, pode ser feito um encerramento em camada única da parede vaginal. Pode ser utilizado um ponto de colchoeiro evitado contínuo sem travamento ou pontos interrompidos de uma sutura como a Sutura Coated VICRYL 2-0 ou a Sutura Coated VICRYL Plus 2-0.

Reparação Vaginal Posterior

Quando é apenas necessário o reforço da parede vaginal posterior, utilize somente o Sistema de Reparação do Pavimento Pélvico Posterior GYNECARE PROSIMA. Este contém 1 Implante de Rede e um Introdutor Posterior concebido especialmente para ser utilizado numa reparação vaginal posterior. Depois de fazer as disseções e incisões vaginais necessárias, cre canais teciduais no compartimento posterior para colocar as tiras do Implante de Rede. **NOTA: O Introdutor Posterior não deve ser usado para dissecar tecidos.**

Dissecção Vaginal Posterior e do Canal

Dissecte o epitélio vaginal posterior do tecido pré-rectal. Como sucede na parede vaginal anterior, deve dissecar-se a parede vaginal posterior em toda a espessura. Esta dissecação deve ser facilitada por hidrodissecção subepitelial. Continue com a dissecação para fora em cada lado, até aos músculos elevadores do ânus, ao nível da espinha isquiatca. Prossiga depois com a dissecação através de cada um dos pilares rectos e ate, mas não ultrapassando, cada um dos ligamentos sacrospinais, criando canais nos quais serão colocadas as tiras do Implante de Rede. Consultar a figura 9A.

O tratamento do enterocelo pré-existente é opcional, mas se for efectuado pode só-lo nesta fase, de acordo com a técnica preferida do cirurgião.

Se a cavidade peritoneal for aberta durante a dissecação anterior ou posterior, ela deve ser encerrada antes da colocação da rede.

Colocação do Implante de Rede Posterior

Não é necessária plicação do tecido pré-rectal. Todavia, se for feita plicação do tecido pré-rectal, só é plicada a zona central deste tecido. Tal evita que a área dissecada se torne demasiado estreita. Coloque o Implante de Rede por cima do tecido pré-rectal, com as bolsas das tiras viradas para cima. Caso se pretenda fixar com sutura, tal deve ser feito neste momento do procedimento colocando uma sutura como a Sutura MONOCRYL 2-0 ou a Sutura Coated VICRYL 2-0 no ápex da vagina e enfiando-a através da aba apical do Implante de Rede. A sutura pode ser atada neste momento ou depois de colocadas as tiras. A fixação do entalhe distal do Implante de Rede é opcional e pode ser feita com uma sutura como a Sutura MONOCRYL 2-0 ou a Sutura Coated VICRYL 2-0.

Utilizando o Introdutor Posterior, coloque as tiras do Implante de Rede em cada canal direito e esquerdo criado pela dissecação em direcção a cada ligamento sacrospinal (conforme descrito acima). Agarre no Introdutor Posterior utilizando um porta-agulhas recto, conforme mostrado na figura 9B. **NOTA: Coloque a ponta do porta-agulhas no interior da extremidade recta entalhada do Introdutor Posterior.** Assegure-se de que o Introdutor Posterior conectado está alinhado com a pega do porta-agulhas. Introduza a ponta do Introdutor Posterior na bolsa da tira no lado direito da doente (consultar a figura 9B). Depois, direcione o Introdutor Posterior, com a tira carregada, para o canal tecidual previamente criado (consultar a figura 9C) mantendo a posição da pega do porta-agulhas na vertical. Prossiga para inserir a totalidade do comprimento da tira no canal, de forma a que a base da tira atinja o limite superior da dissecação fascial. **NOTA: Insira completamente a primeira tira. Se o Introdutor for puxado e retirado antes de a tira chegar ao local pretendido, será necessário remover a tira, voltar a carregá-la e a inseri-la.** **NOTA: Tome precaução para não inserir demasiado profundo, de modo a evitar lesões em estruturas teciduais críticas. NOTA: Se for encontrada resistência durante a inserção das tiras, determine a causa da resistência antes de prosseguir. Continuar a avançar o Introdutor contra resistência pode provocar danos no Implante de Rede ou uma inserção excessiva, provocando lesões em estruturas teciduais críticas.** Retire o Introdutor Posterior ao longo do trajeto de inserção, deixando a tira no canal. As tiras ficam apostas, mas não penetram nos ligamentos sacrospinais. Não coloque suturas nos ligamentos sacrospinais. Repita o procedimento do lado esquerdo da doente com a segunda tira. Na figura 9D mostram-se as duas tiras colocadas. **NOTA: Durante a colocação da segunda tira, tome precaução para evitar o movimento do Implante de Rede e confirme que o Implante de Rede NÃO ESTÁ torcido.**

Posicione o corpo do Implante de Rede livremente por cima da fáscia vaginal subjacente. Evite dobrar ou torcer o corpo e as tiras do Implante de Rede. Pode ser necessário cortar o corpo do Implante de Rede, dependendo das dimensões vaginais ou da quantidade de dissecação lateral. O epitélio da parede vaginal posterior pode ser cortado, mas deve evitar-

se uma remoção excessiva de epitélio vaginal. Encerre o epitélio da parede vaginal posterior por cima do Implante de Rede, sem a utilização de suturas de travamento (conforme descrito em baixo). A colocação final do Implante de Rede no compartimento posterior é mostrada na figura 9E.

NOTA: Assegure-se de que é obtida a hemostase antes e durante o encerramento das incisões vaginais.

Encerre as incisões vaginais sem utilizar suturas de travamento ou “em oito”, para evitar a desvascularização do epitélio vaginal ao longo das linhas de incisão e reduzir a erosão da rede. Preferivelmente, encerre o epitélio em 2 planos para se obter uma linha de sutura relativamente grossa no local da incisão vaginal. Encerre a camada mais profunda utilizando um ponto sem travamento subepitelial contínuo com uma sutura como a Sutura MONOCRYL 2-0 ou a Sutura Antibacteriana MONOCRYL Plus 2-0. O epitélio é depois encerrado utilizando um ponto de colchoeiro evertido contínuo sem travamento, utilizando uma sutura como a Sutura Coated VICRYL 2-0 ou a Sutura Coated VICRYL Plus 2-0. **NOTA: Coloque o Implante de Rede nos 2/3 superiores da vagina, tendo o cuidado de cortar o Implante de Rede se este ultrapassar os 2/3 superiores.** No final da cirurgia, recomenda-se exame com toque rectal para excluir lesão rectal.

Em alternativa, pode ser feito um encerramento em camada única da parede vaginal. Pode ser utilizado um ponto de colchoeiro evertido contínuo sem travamento ou pontos interrompidos de uma sutura como a Sutura Coated VICRYL 2-0 ou a Sutura Coated VICRYL Plus 2-0.

Reparação Vaginal Anterior e Posterior Combinada

Quando é necessário o reforço da parede vaginal anterior e posterior, utiliza-se o Sistema de Reparação do Pavimento Pélvico Combinado GYNECARE PROSIMA. Este contém 2 Implantes de Rede idênticos, um para a reparação vaginal anterior e o segundo para a reparação vaginal posterior. Utilize apenas o Introdutor Anterior curvado para a reparação anterior e apenas o Introdutor Posterior recto para a reparação posterior. Efectue as reparações vaginais anterior e posterior conforme acima descrito. Recomenda-se que a reparação vaginal anterior seja efectuada em primeiro lugar. A colocação final dos Implantes de Rede nos compartimentos anterior e posterior é mostrada na figura 10. Após a conclusão da cirurgia, recomenda-se uma cistoscopia para excluir lesão do aparelho urinário. É necessário exame com toque rectal para excluir lesão rectal.

Utilização do Sistema GYNECARE PROSIMA com Conservação do Útero (Histeropexia)

Caso se conserve o útero prolapsoado, a aba apical do Implante de Rede deve ser fixa ao colo do útero. A fixação do Implante de Rede ao colo do útero deve ocorrer ao nível do anel pubo-cervical, quando colocado durante a reparação vaginal anterior ou posterior.

Quando o útero é conservado durante uma reparação vaginal anterior, o anel pubo-cervical é exposto durante a dissecação vaginal anterior. Coloque uma Sutura PROLENE 2-0 firmemente na face anterior do anel pubo-cervical. Esta sutura também é colocada através da aba apical do Implante de Rede. A Sutura PROLENE na aba é atada, depois de as tiras do Implante de Rede estarem colocadas. Isto fixa o Implante de Rede à superfície anterior do colo do útero, ao nível do anel pubo-cervical, e garante que o Implante de Rede se distende com a vagina, dado que o VSD fica posicionado correctamente.

Na reparação posterior, fixe o Implante de Rede ao colo do útero posterior ao nível do anel pubo-cervical ou acima deste. O fundo de saco de Douglas pode ser aberto durante a fixação do Implante de Rede ao colo do útero. Encerre o peritónio do fundo de saco acima desta sutura para prevenir a aderência do intestino ao Implante de Rede. Se o cirurgião optar por não abrir o fundo de saco de Douglas, o anel pubo-cervical é exposto durante a dissecação vaginal posterior. Uma Sutura PROLENE 2-0 é colocada firmemente na face posterior do anel pubo-cervical. Esta sutura também é colocada através da aba apical do Implante de Rede. A Sutura PROLENE é atada, depois de as tiras do Implante de Rede estarem colocadas. Isto fixa o Implante de Rede à superfície posterior do colo do útero, ao nível do anel pubo-cervical.

Quando são utilizados para reparações vaginais anterior e posterior, os Implantes de Rede devem ser fixos às faces anterior e posterior do colo do útero, conforme descrito acima (consultar a figura 11).

Higiene do Implante de Rede

Durante a cirurgia, irrigue as feridas vaginais com solução salina. Mantenha o manuseamento do Implante de Rede ao mínimo necessário e pratique uma boa higiene da rede.

Colocação do VSD e Balão

No momento de conclusão da cirurgia, coloque um VSD de tamanho adequado com Balão fixo na vagina e suture-o em posição para prevenir o deslocamento. O VSD tem 3 tamanhos possíveis (pequeno, médio e grande) e pode ser personalizado pelo cirurgião para se adequar ao comprimento vaginal da doente, da forma que se segue.

Ajuste e Corte do VSD

O VSD é fornecido no seu tamanho maior. Determine o tamanho adequado do VSD para a doente utilizando o próprio VSD para avaliar o ajuste à doente. Tal é feito colocando o VSD de tamanho grande na vagina, entre o apex distendido e o anel himenal. Para inserir o VSD na vagina, agarre na zona mais larga do VSD e dobre ao longo do eixo longitudinal, com o Balão virado para cima (consultar a figura 12). A zona mais larga do VSD é inserida em primeiro lugar, de tal forma que os orifícios de sutura ficam situados imediatamente acima do anel himenal. **NOTA: Não retire nem danifique o Balão durante o dimensionamento do VSD.** O tamanho adequado é obtido quando o VSD se ajustar firmemente nos 2/3 superiores da vagina distendida, com a extremidade distal e ilhós de sutura 1 cm acima do anel himenal (consultar a figura 13).

Se o tamanho grande se ajustar, o VSD não é modificado. Se for necessário o tamanho médio, a secção mais superior é recortada cuidadosamente, utilizando apenas a ponta da tesoura Mayo curva para fazer pequenos cortes e garantir uma extremidade de corte regular. Deve tomar-se precaução para minimizar a quantidade de material que permanece nas áreas cortadas. **NOTA: É importante ajustar o VSD muito cuidadosamente. Depois de cortado, não é possível aumentar um VSD e as secções cortadas não podem ser novamente fixas.** Afaste o Balão durante o corte (consultar a figura 14). **Deve tomar-se precaução para evitar danificar o Balão durante o corte do VSD.**

Se o tamanho médio se ajustar, não são necessários cortes adicionais. Se for necessário o tamanho pequeno, a secção restante é retirada do modo acima descrito. Afaste o Balão durante o corte para evitar que se danifique.

Depois de o VSD ser correctamente dimensionado e o Balão reposicionado, o conjunto pode ser inserido na vagina da doente. **NOTA: Para minimizar o risco de perfuração do Balão, não utilize nenhum instrumento para ajudar na inserção do VSD ou do Balão.** Se o Balão se danificar, retire o Balão do VSD e utilize compressas para preencher a cavidade vaginal.

Depois de o conjunto estar adequadamente posicionado nos 2/3 superiores da vagina distendida da doente, fixe o VSD colocando um único fio de sutura através do ilhó de sutura do VSD em direcção ao epitélio da parede vaginal posterior, para fora e para cima do hímen bilateralmente, conforme se mostra na figura 15, nas posições das 4 e 8 horas. As suturas direita e esquerda são depois atadas uma de cada vez, mantendo o VSD firmemente posicionado no interior da vagina. **NOTA: Tome precaução para não punccionar o Balão quando suturar o VSD na sua posição.** Para esta aplicação, recomenda-se uma sutura como a Sutura Coated VICRYL 2-0 ou uma sutura absorvível equivalente.

Insuflação do Balão

Depois de suturar o VSD em posição, coloque a seringa de 50 ml fornecida rodando-a para a fixar na válvula do Balão. **NOTA: Após a colocação do VSD, é necessária a colocação de uma algaia para evitar a retenção urinária.** Após insuflação com um pequeno volume de ar ambiente (consultar a figura 16), palpe a totalidade do comprimento do Balão com o dedo para garantir que o Balão foi accionado e está assente em toda a extensão da vagina. Depois de confirmada a colocação, retire o dedo e continue a insuflar totalmente o Balão até que caiba apenas uma ponta do dedo no intêito entre o Balão e a parede vaginal. Recomenda-se a estabilização do VSD à medida que ocorre a insuflação. O Balão insuflado serve para promover a aposição entre o Implante de Rede e a parede vaginal. O volume de ar necessário para uma insuflação suficiente do Balão varia de doente para doente. **NOTA: O volume máximo de insuflação do Balão não deve exceder 90 ml.** Depois de estar adequadamente insuflado, retire a seringa da válvula, rodando. A linha de insuflação do Balão tem que se estender para fora da vagina e ser fixada à coxa da doente. A tampa deve ser colocada na válvula do Balão, para garantir que o Balão irá manter o volume de ar pretendido (consultar a figura 7). **NOTA: Não aperte demasiado a tampa.** Se for necessário, o Balão pode ser ajustado posteriormente, utilizando uma seringa padrão para aumentar ou diminuir o volume de ar no interior do Balão. O Balão pode ser palpado ou inspecionado visualmente em qualquer momento, para garantir que mantém insuflação suficiente. **NOTA: À medida que o doente se movimenta, o Balão irá assentar na cavidade vaginal e pode parecer aumentar ou diminuir de pressão. Esta situação é normal.**

NOTA: Não destaque o Balão do VSD antes de utilizar.

NOTA: Não insufla o Balão antes da sua introdução na vagina.

NOTA: Após a insuflação do Balão, se os ilhós de sutura do VSD se tiverem movido mais do que 1 cm por cima do anel himenal ou caso exista uma tensão excessiva nas suturas dos ilhós, diminua a pressão no Balão e, se for necessário, reposicione ou redimensione o VSD.

NOTA: Se forem observados orifícios no Balão, se for detectada uma fuga ou se o Balão não se mantiver expandido após a insuflação, NÃO utilize o Balão. Este deve ser removido do VSD e eliminado da forma adequada. Utilize o enchimento com compressas padrão, em vez do Balão.

NOTA: Se o rolhão conectar do Balão se separar do VSD, deve ser empurrado para o seu lugar.

NOTA: Não fixe a linha de insuflação do Balão na vagina.

NOTA: Para prevenir danos, nunca aplique forças extremas de dobragem, tensão ou torção na linha de insuflação.

NOTA: Não utilize enchimento por compressas na presença de um Balão.

Remoção do Balão do VSD

Utilizando uma seringa padrão, desinsufla totalmente e retire o Balão 1 dia após a cirurgia, deixando o VSD colocado. **NOTA: Não deixe o Balão no interior da vagina durante um período superior a 1 dia.**

1) Retire a tampa da válvula do Balão.

2) Coloque uma seringa padrão de 50 ml (ou maior) na válvula do Balão e desinsufla completamente o Balão (consultar a figura 17). É importante desinsuflar completamente o Balão antes de o tentar remover do VSD. **NOTA: Um balão completamente desinsuflado irá fazer com que o êmbolo da seringa recue após a remoção de todo o ar.**

3) Retire a seringa.

4) O Balão pode ser depois separado do VSD e retirado da doente puxando suavemente na direcção caudal, a linha de insuflação, numa zona próxima do rolhão conector do Balão, aplicando em simultâneo uma contra-tracção suave na extremidade distal do VSD com o dedo. Consultar a figura 18.

NOTA: Não faça recuar o Balão, a não ser que este esteja totalmente desinsuflado e não se sinta nenhuma resistência. Se for encontrada resistência, determine a sua causa antes de prosseguir. Continuar a fazer avançar ou recuar o Balão contra resistência pode originar movimentos do VSD ou lesões teciduais na cavidade vaginal. Para garantir que ocorreu uma desinsuflação completa, volte a conectar a seringa e retire todo o ar antes de prosseguir com a remoção.

Remoção do VSD da Doente

Retire o VSD da doente cerca de 3 a 4 semanas após a cirurgia, depois de ter ocorrido uma cicatrização suficiente. Neste momento, as suturas absorvíveis podem ter-se dissolvido ou perdido força tensil suficiente para permitir uma fácil remoção do VSD, sem qualquer resistência por parte das suturas. **NOTA: Pode ser necessário cortar ambas as suturas para tornar possível a remoção.** **NOTA: Não deixe o VSD no interior da vagina durante um período superior a 4 semanas.** Retire todas as suturas de fixação do VSD restantes. Retire manualmente o VSD do canal vaginal, conforme se mostra na figura 19.

Cuidados Peri-operatórios

As doentes podem receber antibióticos profiláticos, administrados de acordo com a prática habitual do cirurgião. Os antibióticos podem ser mantidos no pós-operatório, dependendo da preferência do cirurgião. Pode utilizar-se profilaxia tromboembólica.

O cirurgião deve explicar a finalidade do VSD, que permanece na vagina durante um período máximo de quatro semanas depois da cirurgia, e que se destina a actuar como suporte da vagina contra a rede durante o período de cicatrização. A doente deve ser informada de que o VSD será retirado durante uma avaliação pós-operatória, que terá lugar aproximadamente 4 semanas depois da cirurgia. A doente deve ser informada de que poderá desenvolver corrimento vaginal no pós-operatório e que o VSD se poderá mover ligeiramente para baixo. Caso a doente sinta que o VSD se moveu para baixo, poderá empurrá-lo suavemente para cima, para uma posição mais confortável. Todavia, se o VSD estiver a provocar um desconforto significativo, a doente deverá ser aconselhada a entrar em contacto com o seu médico.

Após a alta hospitalar, a doente deve ser instruída no sentido de evitar actividades vigorosas durante um período de 3 a 4 semanas. Nessa altura, os tecidos pélvicos ter-se-ão incorporado no Implante de Rede e a doente poderá retornar às suas actividades normais do dia-a-dia. A doente deve ser aconselhada a evitar relações sexuais durante um período mínimo de 6 semanas após a cirurgia. Os exercícios destinados ao pavimento pélvico podem ser recomendados em qualquer momento após a cirurgia.

ACTUAÇÃO

Estudos feitos em animais mostram que a implantação da GYNECARE GYNEMESH PS provoca uma reacção inflamatória miríma a ligera, a qual é passageira e é seguida do depósito de uma fina camada fibrosa de tecido que pode crescer através dos intervalos da rede, incorporando assim a rede no tecido adjacente. A rede mantém-se macia e flexível, não se verificando dificuldades no processo de cicatrização normal da ferida. O material não é absorvido nem está sujeito a degradação ou enfraquecimento pela acção das enzimas dos tecidos.

CONTRA-INDICAÇÕES

- Quando a GYNECARE GYNEMESH PS é utilizada em lactentes, crianças, mulheres grávidas ou que pretendam engravidar futuramente, o cirurgião deverá estar ciente de que este produto não tem elasticidade suficiente para acompanhar o crescimento da doente.
- O Sistema GYNECARE PROSIMA não deve ser utilizado na presença de gravidez ou de infecções purulentas ou neoplasias malignas da vagina, colo do útero ou útero.

ADVERTÊNCIAS E PRECAUÇÕES

- Antes de utilizar os Sistemas GYNECARE PROSIMA, os utilizadores devem estar familiarizados com as técnicas e os procedimentos cirúrgicos que envolvem a reparação do pavimento pélvico e redes não absorvíveis.
- A utilização do Sistema GYNECARE PROSIMA não foi totalmente avaliada em doentes apresentando prolapso dos órgãos pélvicos em Estádio IV. Por conseguinte, não se recomenda a sua utilização nestas doentes.
- Devem ser seguidas práticas cirúrgicas aceitáveis para o Sistema GYNECARE PROSIMA, assim como para o tratamento de feridas infectadas ou contaminadas.
- Não utilize o Sistema GYNECARE PROSIMA caso pense que o local cirúrgico possa estar infectado ou contaminado. Se o Implante de Rede ou Conjunto VSD-Balão for utilizado em áreas contaminadas, o cirurgião deverá estar ciente de que, em caso de infecção subsequente, poderá ser necessário proceder à sua remoção.
- No pós-operatório deverá ser recomendado à doente que se abstenha de levantar pesos e/ou fazer exercícios físicos (como ciclismo e correr) durante 3 a 4 semanas, e que se abstenha de ter relações sexuais durante 6 semanas ou até que o médico determine ser adequado para a doente voltar às suas actividades normais.
- Não deixar o VSD no interior da vagina durante um período superior a 4 semanas.
- Não deixar o Balão no interior da vagina durante um período superior a 1 dia.
- Os componentes do Sistema GYNECARE PROSIMA não se destinam a ser utilizados com dispositivos diferentes dos mencionados neste folheto informativo.
- Deve evitar-se aplicar uma tensão excessiva no implante de rede durante o manuseamento.
- Utilizar os Sistemas GYNECARE PROSIMA com precaução e tendo em atenção a anatomia da doente, de forma a evitar lesões em vasos, nervos, bexiga, intestinos e perfuração da parede vaginal. A utilização correcta dos componentes do Sistema GYNECARE PROSIMA irá minimizar os riscos.
- Insuflar o Balão apenas com ar ambiente.
- A palpação irá confirmar que o Balão não contém quaisquer fugas de ar depois da insuflação. A perda completa da insuflação pode limitar a eficácia do Balão.
- A parede do Balão é fina de modo a obter as propriedades desejadas. Punções, cortes, fissuras, compressão ou estiramento excessivo do balão podem conduzir a perda de insuflação. O Balão pode ser facilmente penetrado por uma agulha ou bisturi ou pode ocorrer rotura por manuseamento com um instrumento rombo. Deve tomar-se precaução durante o manuseamento para evitar estas situações. Um Balão danificado não deve ser usado. Retire o balão e preencha com compressas.
- O volume máximo de insuflação do Balão é de 90 ml. Não insuflar o balão em excesso. Uma insuflação excessiva do Balão pode provocar desconforto na doente, necrose tecidual, rotura da ferida vaginal no pós-operatório ou incapacidade miccional.
- Não utilizar os Sistemas GYNECARE PROSIMA em doentes submetidas a terapêutica anticoagulante.
- Pode ocorrer hemorragia no pós-operatório. Ter atenção a quaisquer sintomas ou sinais antes de dar alta à doente.
- Se ocorrer dor insuflar, hemorragia ou outros problemas, a doente deverá ser instruída a contactar imediatamente o cirurgião.
- Embora seja improvável que ocorram lesões vesicais com esta técnica, recomenda-se a realização de cistoscopia.
- Embora seja improvável que ocorram lesões rectais com esta técnica, recomenda-se a realização de um exame com toque rectal.
- Evitar o contacto do Implante de Rede GYNECARE GYNEMESH PS com agraços, pinças ou clamps de todo o tipo, uma vez que isso poderá causar danos mecânicos na rede.
- O Implante de Rede não deve estar presente no 1/3 inferior da vagina. Se for necessário, cortar o Implante de Rede na junção do 1/3 inferior e médio da parede vaginal.
- Podem ser administrados antibióticos profiláticos, de acordo com a prática habitual do cirurgião.

REAÇÕES ADVERSAS

- As reacções adversas potenciais são aquelas tipicamente associadas a materiais cirurgicamente implantáveis, incluindo potenciação de infecção, inflamação, formação de aderências, formação de fistulas, erosão, extrusão e formação de tecido cicatricial originando contração do implante.
- As reacções adversas potenciais são aquelas tipicamente associadas aos procedimentos de reparação do prolapso de órgãos pélvicos, incluindo dor durante as relações sexuais e dor pélvica. Estas podem resolver-se espontaneamente no decurso do tempo.
- Podem ocorrer punções ou lacerações ou lesão de vasos, nervos, bexiga, uretra ou intestino durante a dissecação ou colocação da rede, que podem exigir reparação cirúrgica.
- No caso dos procedimentos de reparação do pavimento pélvico, a dissecação tem potencial para provocar incapacidade da micção normal durante um período de tempo variável.

ESTERILIZAÇÃO

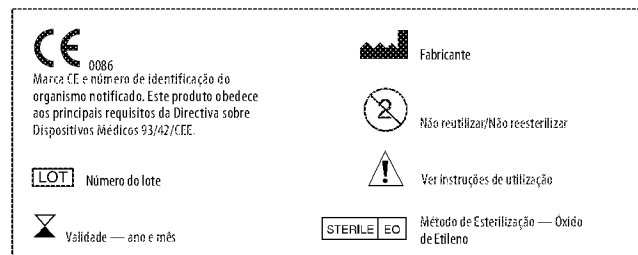
Os Sistemas GYNECARE PROSIMA são esterilizados com óxido de etileno. NÃO REESTERILIZAR nenhuma parte do Sistema GYNECARE PROSIMA. NÃO REUTILIZAR nenhuma parte do Sistema GYNECARE PROSIMA. A reutilização deste dispositivo (ou de partes deste dispositivo) pode criar um risco de degradação do produto e contaminação cruzada, o que pode conduzir a infecção ou transmissão de agentes patogénicos transmitidos pelo sangue aos doentes e utilizadores. Não utilizar se a embalagem estiver aberta ou danificada. Descartar todos os componentes do Sistema GYNECARE PROSIMA abertos, que tenham sido utilizados ou não.

ELIMINAÇÃO

Descartar os componentes do Sistema GYNECARE PROSIMA e as embalagens de acordo com a política e os procedimentos em vigor na instituição relativamente a materiais e resíduos de risco biológico.

ARMAZENAMENTO

Condições recomendadas de armazenamento: temperatura ambiente controlada e humidade relativa (aproximadamente 25 °C, 60 % de humidade relativa), ao abrigo da humidade e do calor directo. Não utilizar para além do prazo de validade.

Símbolos utilizados nas etiquetas



Sistema de reparación del suelo pélvico anterior
Sistema de reparación del suelo pélvico posterior
Sistema de reparación del suelo pélvico combinado

Por favor lea con atención toda la información.

De no seguir las instrucciones correctamente, los dispositivos podrían no funcionar adecuadamente e incluso causar lesiones.

ATENCIÓN: las leyes federales de los EE.UU. restringen la venta de este dispositivo al personal facultativo o bajo su prescripción.

Se recomienda recibir la instrucción adecuada antes de utilizar los sistemas de reparación del suelo pélvico GYNECARE PROSIMA™. Coordine la instrucción con el representante de ventas de su compañía.

INDICACIONES

Los sistemas de reparación del suelo pélvico GYNECARE PROSIMA, a través de la colocación de implantes de malla blanda PROLENE™ no absorbibles GYNECARE GYNEMESH™ PS, están indicados para el refuerzo del tejido y la estabilización prolongada de las estructuras fasciales del suelo pélvico, ya sea como soporte mecánico o como material de unión para el defecto fascial. Los sistemas permiten el mantenimiento del conducto vaginal durante el período de cicatrización después de la reparación quirúrgica del prolapso de la pared vaginal y, al mismo tiempo, mantienen los implantes de malla en su lugar.

DESCRIPCIÓN

Los sistemas de reparación del suelo pélvico anterior, posterior y combinado GYNECARE PROSIMA constan de implantes de malla GYNECARE GYNEMESH PS previamente cortados y de instrumental para facilitar su colocación y mantenimiento postoperatorio (véase la figura 1). En la siguiente tabla se resumen los componentes incluidos en cada sistema:

SISTEMA DE REPARACIÓN DEL SUELO PÉLVICO	COMPONENTES (véase la figura 1)				
	Implante de malla en portaimplante (A)	Conjunto de dispositivo de soporte vaginal y balón (B y C)	Insertador anterior (D)	Insertador posterior (E)	Jeringa (F)
Anterior	1	1	1		1
Posterior	1	1		1	1
Combinado	2	1	1	1	1

Tabla 1 – Componentes del sistema de reparación del suelo pélvico GYNECARE PROSIMA

GYNECARE GYNEMESH PS

La malla GYNECARE GYNEMESH PS está fabricada con filamentos tejidos de polipropileno extruido de composición idéntica a la utilizada en la sutura de polipropileno PROLENE™ (ETHICON, INC.). Según se ha comprobado, este material no es reactivo cuando se emplea como sutura y conserva su resistencia indefinidamente en el uso clínico. La malla ofrece una resistencia, durabilidad y adaptabilidad quirúrgica excelentes, con suficiente porosidad para la necesaria integración del tejido. Contiene además monofilamentos de sutura PROLENE de color azul que forman líneas de contraste con el resto de la malla. Esta está fabricada con fibras monofilamento de diámetro reducido tejidas con un diseño único, que le otorga una flexibilidad casi un 50 por ciento superior a la de la malla de polipropileno PROLENE™ común. La malla está tejida mediante un proceso que entrelaza la unión de cada fibra y proporciona elasticidad en ambas direcciones. Esta construcción permite cortar la malla en cualquier forma o tamaño deseados sin que se desenrede. La elasticidad bidireccional le permite adaptarse a las diferentes tensiones presentes en el cuerpo.

Implante de malla

Los implantes de malla están fabricados con GYNECARE GYNEMESH PS y vienen previamente cortados en forma de "Y" para la reparación de los defectos vaginales anteriores, posteriores y apicales. Véase la figura 2. Los implantes de malla tienen dos tiras y un cuerpo central. En el extremo proximal tienen una lengüeta apical para poder fijarlos con sutura y reducir al mínimo su movimiento durante la colocación de las tiras. Además, en el extremo distal tienen un surco para facilitar su alineación. Las tiras de los implantes de malla tienen bolsillos preformados para permitir su colocación con los insertadores. Los implantes de malla se suministran en un portaimplante de Tyvek® no revestido y una película de plástico transparente, diseñado para facilitar su extracción.

Insertador anterior

El insertador anterior es un instrumento para uso en una sola paciente diseñado para facilitar la inserción de las tiras del implante de malla en los canales de tejido disecado anteriores. **NOTA: el insertador anterior no está diseñado para diseccionar tejido.** Está diseñado para ser compatible con los bolsillos del implante de malla para permitir la colocación de las tiras a ambos lados de la paciente en el compartimento anterior. Véase a las figuras 3 y 4.

Insertador posterior

El insertador posterior es un instrumento para uso en una sola paciente diseñado para facilitar la inserción de las tiras del implante de malla en los canales de tejido disecado posteriores. **NOTA: el insertador posterior no está diseñado para diseccionar tejido.** Tiene fijado una guía o porta aguja estándar como estabilizador para controlar su inserción. El insertador posterior está diseñado para ser compatible con los bolsillos del implante de malla para permitir la colocación de las tiras a ambos lados de la paciente en el compartimento posterior. Véase a la figura 5.

Dispositivo de soporte vaginal (VSD)

El VSD es un dispositivo para uso en una sola paciente diseñado para el soporte postoperatorio de los tejidos vaginales después de la colocación de la malla y el cierre de las incisiones vaginales. El extremo apical es el extremo más ancho del VSD y contiene secciones recortables. Después del ajuste inicial del VSD en la paciente, puede continuar ajustándose a su anatomía recortando las secciones apicales designadas. El VSD se aloja en los dos tercios superiores de la vagina de la paciente durante 3 a 4 semanas y posteriormente se extrae. Véase a la figura 6.

Balón

El balón es un dispositivo para uso en una sola paciente diseñado para sustituir el relleno de gasa vaginal posquirúrgico. El volumen del balón puede ajustarse para llenar el conducto vaginal y mantener apoyados la pared vaginal y el implante de malla. El balón se suministra previamente fijado al VSD. La figura 7 muestra el balón desinflado sin el VSD. El balón se deja en la paciente hasta 1 día como máximo.

Jeringa

Se suministra una jeringa de 50 ml para inflar el balón.

SECCIÓN 1: PRINCIPIOS DEL PROCEDIMIENTO CON EL SISTEMA GYNECARE PROSIMA

El objetivo del procedimiento de reparación del suelo pélvico con el sistema GYNECARE PROSIMA es lograr una reparación anatómica duradera y estandarizada del prolapso del órgano pélvico. Según el lugar del prolapso y la preferencia del cirujano, la reparación puede ser anterior y/o posterior. La histerectomía o la conservación del útero pueden combinarse con el procedimiento con el sistema GYNECARE PROSIMA. Si está indicado, puede realizarse una reparación perineal o un cabestrillo suburetral para el tratamiento de la incontinencia urinaria por estrés simultáneamente cuando se utiliza el sistema GYNECARE PROSIMA. Puede utilizarse un cabestrillo suburetral por vía retropúbica o transobturadora.

La reparación del prolapso se logra mediante la colocación de uno o dos implantes de malla a través de un abordaje vaginal. Al finalizar la cirugía, se coloca en la vagina un VSD con un balón inflable para ajustar su tamaño y se lo sutura para que actúe como soporte de la vagina y los implantes de malla durante la integración del tejido. Una vez inflado, el balón sustituye el relleno de gasa tradicional llenando la cavidad vaginal y manteniendo los implantes de malla apoyados contra la vagina. El día después de la cirugía, el balón se desinfla y se retira de la vagina sin quitar el VSD. El VSD se deja en su lugar hasta 4 semanas después de la cirugía, mientras el tejido se integra a los implantes de malla.

SECCIÓN 2: FUNDAMENTOS DEL SISTEMA GYNECARE PROSIMA

Después de una cirugía convencional de prolapso del órgano pélvico, los tejidos reparados están expuestos a aumentos en la presión intraabdominal cuando la paciente se moviliza, tose, vomita y hace un esfuerzo al evacuar los intestinos. Estos aumentos en la presión intraabdominal pueden afectar adversamente a la cicatrización de la reparación vaginal y producir el fallo quirúrgico y un prolapso recurrente. El sistema GYNECARE PROSIMA refuerza la reparación vaginal con el implante de malla y utiliza el VSD como soporte de la vagina durante 3 a 4 semanas después de la cirugía con el objeto de reducir el riesgo de fallo quirúrgico y prolapso recurrente.

Durante la reparación vaginal anterior el cuerpo del implante de malla debe colocarse sin tensión entre la vejiga urinaria y los dos tercios superiores de la vagina, extendiéndolo lateralmente a la altura del arco tendinoso de la fascia pélvica. Durante la reparación vaginal posterior el cuerpo del implante de malla debe colocarse sin tensión entre el recto y los dos tercios superiores de la vagina, ajustándolo lateralmente sobre los músculos elevadores del ano. La sección apical del cuerpo del implante de malla está diseñada para llegar hasta el ápice vaginal. En posición anterior, el implante de malla puede fijarse con sutura al tejido prevesical o al cuello uterino. En posición posterior, puede fijarse al tejido prerrectal o al cuello uterino.

El VSD sirve de soporte a los tejidos vaginales después de la cirugía y los mantiene apoyados contra el implante de malla hasta que se integren a ella. La integración del tejido a través del implante de malla se produce dentro de las 3 a 4 semanas de la cirugía. El uso del sistema GYNECARE PROSIMA evita la necesidad de realizar una disección fuera de la cavidad pélvica y de pasar sutura e instrumental a través del agujero obturador y el ligamento sacroespinoso, lo cual hace que la cirugía sea más sencilla de realizar.

Histerectomía

La preferencia del cirujano y las necesidades de la paciente determinarán si es necesario realizar una histerectomía concomitante. Cuando se realiza una histerectomía, se recomienda el cierre del peritoneo del fondo de saco para evitar el contacto del implante de malla con los intestinos. Debe evitarse realizar un cierre con incisión en "T" ya que esto puede aumentar el riesgo de exposición de la malla. Cuando se realiza una histerectomía vaginal junto con una reparación anterior o posterior, o ambas, primero debe cerrarse la incisión de la histerectomía de forma transversal y, posteriormente, deben realizarse las incisiones de reparación de forma tal que no estén conectadas con la incisión de la histerectomía previamente cerrada. De esta manera se evita la realización de una incisión en "T".

Conservación del útero

El sistema GYNECARE PROSIMA es adecuado para aquellos casos en que el cirujano o la paciente prefieren conservar el útero.

Incisiones vaginales

Las incisiones vaginales del procedimiento con el sistema GYNECARE PROSIMA son las mismas que se utilizan en las cirugías de reparación vaginal rutinarias. Las incisiones deben realizarse hasta la máxima profundidad de la pared vaginal para reducir el potencial de exposición de la malla.

Colocación del implante de malla

Los implantes de malla son mantenidos en su lugar por el VSD hasta que se produce la integración del tejido. Por lo tanto, no es necesario fijar las tiras del implante de malla en su lugar. La parte apical del implante de malla puede fijarse sobre la fascia en la línea media del ápice vaginal utilizando sutura del tipo MGHOCRYL™ 2-0 (poliglicaprona 25) o Coated VICRYL™ 2-0 (poliglactina 910). El epitelio vaginal no debe suturarse sobre el implante de malla.

Preservación de la vagina

Debe evitarse retirar o extirpar demasiado epitelio vaginal. Si se retira demasiado epitelio vaginal, puede producirse cierta retracción del tejido después de la cirugía y reducirse aún más la capacidad vaginal.

Tres niveles de soporte vaginal

Se conocen tres niveles de soporte para la reparación vaginal. El sistema GYNECARE PROSIMA está diseñado para proporcionar el nivel I y II de soporte en el procedimiento, según se indica a continuación:

Nivel I – Suspensión y soporte (tercio superior de la vagina)

El tercio superior de la vagina (incluida la bóveda vaginal después de la histerectomía) y el útero son apoyados por dos mecanismos. En primer lugar, el apoyo directo para el útero y la vagina superior es proporcionado por las fibras del parametrio (ligamentos cardinal y uterosacro) y el paraolpicio. Estas fibras actúan como ligamentos de suspensión y se elevan desde la fascia del músculo piriforme, la articulación sacroilíaca y el sacro lateral y se introducen en el tercio superior lateral de la vagina y en el aspecto posterolateral del cuello uterino. En segundo lugar, el apoyo indirecto para el útero y la vagina superior es proporcionado por la placa elevadora, formada por la fusión de los músculos elevadores del ano derecho e izquierdo entre el recto y el cóxis. El prolapso de la bóveda uterina y vaginal se produce como consecuencia del fallo de estos mecanismos de soporte directos e indirectos. Es probable que implique una debilidad del suelo pélvico muscular y las fibras de suspensión del parametrio y el paraolpicio superior. El objetivo de la cirugía de prolapso de nivel I es recrear los mecanismos de soporte directos e indirectos. El sistema GYNECARE PROSIMA utiliza las tiras de implante de malla que mantienen apoyados los músculos internos obturadores y la fascia parietal superior en la reparación vaginal anterior y, en la reparación vaginal posterior, tiras de implante de malla que mantienen apoyados los ligamentos sacroespinosos. Esto proporciona un soporte directo por suspensión y soporte indirecto creando una amplia área de apoyo para la vagina superior y el útero con el implante de malla.

Nivel II – Fijación lateral (tercio medio de la vagina)

La parte media de la vagina está fijada lateralmente y de forma directa a los músculos de la pared lateral pélvica por el arco tendinoso de la fascia pélvica. A este nivel, las paredes vaginales anterior y posterior se estiran entre las fijaciones laterales a la derecha y a la izquierda. Al nivel II, el objetivo de la reparación del prolapso es volver a fijar la vagina media lateral sobre los músculos de la pared lateral pélvica. Los defectos centrales de la vagina media también requieren soporte al nivel II. El uso del sistema GYNECARE PROSIMA en un procedimiento recrea la fijación lateral de la vagina sobre los músculos de la pared lateral pélvica y, además, proporciona refuerzo fascial central después de la integración de tejido.

Nivel III – Fusión (tercio inferior de la vagina)

NOTA: no se requiere disección en esta área con el sistema GYNECARE PROSIMA.

Al nivel III, en posición anterior, el tercio inferior de la vagina se fusiona con la membrana perineal y la uretra. En posición posterior, el tercio inferior de la vagina se fusiona con el cuerpo perineal y con los músculos elevadores del ano. Los tejidos de esta área se reparan sin implante de malla, ya que éste no está diseñado para ser utilizado en el tercio inferior de la vagina. El sistema GYNECARE PROSIMA no trata los defectos de apoyo al nivel III, aunque pueden tratarse mediante procedimientos concomitantes, como una perineorrafia.

SECCIÓN 3: INSTRUCCIONES DE USO

NOTA: deben consultarse las figuras en divúidas al comienzo de este documento al leer esta sección.

Preparación quirúrgica

La cirugía realizada con el sistema GYNECARE PROSIMA puede llevarse a cabo bajo anestesia general o regional según la preferencia del cirujano, el anestesiólogo y la paciente.

La paciente debe colocarse en posición de litotomía con las nalgas ligeramente por encima de la mesa del quirófano y las caderas flexionadas. A discreción del cirujano, puede drenarse la vejiga. Es necesario utilizar un catéter antes de inflar el balón y puede introducirse en este momento del procedimiento.

Uso del sistema GYNECARE PROSIMA después de una histerectomía**Reparación vaginal anterior**

Cuando sólo se requiere el refuerzo de la pared vaginal anterior, debe utilizarse únicamente el sistema de reparación del suelo pélvico anterior GYNECARE PROSIMA. Este contiene un implante de malla y un insertador anterior especialmente diseñado para utilizar en una reparación vaginal anterior. Una vez realizadas las incisiones y disecciones vaginales requeridas, se crean los canales para el tejido en el compartimento anterior para colocar las tiras de implante de malla usando el insertador anterior. **NOTA: el insertador anterior no se debe utilizar para diseccionar tejido.**

Disección vaginal anterior

El epitelio vaginal anterior se disecciona de la vejiga. Diseque el espesor total de la pared vaginal. Para facilitar este procedimiento debe utilizarse hidrodissección subepitelial. Debe evitarse la disección superficial de la pared vaginal o la separación de la pared vaginal en dos capas ya que podría quedar muy delgada y perder irrigación sanguínea, lo cual aumenta el riesgo de exposición de la malla. Lateralmente, continúe la disección hacia la pared lateral pélvica y hacia la espina isquial.

Disección del canal anterior y colocación del implante de malla

A los efectos de esta descripción, primero realice la disección para la creación de canales para las tiras del implante de malla del lado derecho de la paciente y, a continuación, del lado izquierdo. Estos canales se crean con el objeto de colocar el implante de malla de forma tal que la sección distal de las tiras quede al ras de la pared lateral pélvica y la fascia parietal del músculo interno obturador. Para colocar estas tiras, comience la disección palpando e identificando la espina isquial de ambos lados. **NOTA: como alternativa, esta disección puede comenzarse con un par de tijeras usando una técnica de “empuje y separación”, de forma tal que las puntas de las tijeras siempre queden en posición anterior a la espina isquial.** Siga la disección inicial realizando una disección suave con los dedos hacia la espina isquial. Una vez establecido el contacto con la espina isquial, pase el dedo índice para crear un espacio anterior y superior a la misma. Refiérase a la figura 8A. La dirección de esta disección es perpendicular a la pared lateral pélvica y crea un espacio de aproximadamente 2 cm de anchura y 3 cm de alto. La disección anterior no implica la disección sobre los ligamentos sacroespinosos sino que crea un canal anterior y superior hasta la espina isquial y superficial al arco tendinoso de la fascia pélvica el músculo interno obturador y su fascia parietal. Repita la misma disección del lado izquierdo.

No se requiere el plegue del tejido prevesical. No obstante, en caso de realizar el plegue, sólo debe hacerse en la parte central de dicho tejido para que el área diseccionada no sea demasiado estrecha. Coloque el implante de malla sobre el tejido prevesical de forma tal que los bolsillos de las tiras queden mirando hacia arriba. Si debe fijarse, debe hacerse en este momento del procedimiento con sutura del tipo MONOCRYL 2-0 o Coated VICRYL 2-0 en el ápice de la vagina, pasando las puntadas por la lengüeta apical del implante de malla. Las puntadas pueden atarse en este momento o una vez colocadas las tiras. La fijación del surco distal del implante de malla es opcional y puede hacerse con sutura del tipo MONOCRYL 2-0 o Coated VICRYL 2-0.

Usando el insertador anterior, coloque las tiras de implante de malla dentro de cada canal derecho e izquierdo creado mediante la disección anterior y superior a la espina isquial (según se describe más arriba). **NOTA: los extremos curvos del insertador anterior se doblan en sentidos opuestos y hay flechas en cada extremo que indican la dirección de colocación.** Con la flecha apuntando hacia el lado derecho de la paciente, introduzca la punta del insertador anterior en el bolsillo de la tira del implante de malla (refiérase a la figura 8B) del lado derecho de la paciente. **NOTA: la contracción puede ayudar a mantener el bolsillo cargado sobre el insertador anterior.** Mantenga el insertador anterior en posición vertical, de forma tal que la parte curva del instrumento quede contra la pared vaginal posterior. A continuación, dirija el insertador anterior, con la tira cargada, hacia el interior del canal de tejido previamente creado

(refiérase a la figura 8C) hasta que el mango entre en contacto con los labios mayores del lado contralateral. Para ello, posicione la parte del mango del insertador anterior en sentido vertical de forma tal que el borde de entrada y el bolsillo avancen hacia la espina isquial. Una vez posicionado, incline el mango hacia abajo hasta una posición casi horizontal manteniendo el mango en contacto con el muslo contralateral. **NOTA: la retracción de la vejiga con un instrumento quirúrgico estándar puede ser útil para la colocación inicial en el canal. Si lo desea, utilice el dedo índice en el canal para guiar la colocación inicial del insertador anterior contra los labios mayores del lado contralateral antes de bajar el mango.** Empuje ligeramente hacia arriba para asegurar que los bolsillos de la tira queden bien posicionados y que la sección apical del implante de malla mantenga apoyado el apéndice vaginal. **NOTA: si siente resistencia durante la inserción de la tira, determine la causa antes de continuar. Si sigue haciendo avanzar el insertador a pesar de la resistencia, puede dañar el implante de malla o introducirlo de forma excesiva, lo cual puede dañar las estructuras tisulares críticas.**

Para retirar el insertador anterior, incline el mango hacia atrás a la posición vertical antes de retirarlo, dejando la tira en el canal. **NOTA: inserte la primera tira completamente. NOTA: si quita el insertador anterior antes de colocar la tira del implante de malla en el lugar deseado, deberá retirar la tira y volver a cargarla e insertarla.** Repita este procedimiento del lado opuesto de la paciente dando vuelta el insertador anterior e introduciendo el extremo, con la punta hacia el lado izquierdo de la paciente, en el otro bolsillo. La figura 8D muestra ambas tiras colocadas. **NOTA: durante la colocación de la segunda tira procure evitar el movimiento del implante de malla y compruebe que NO está torcido.**

Posicione el cuerpo del implante de malla de forma holgada sobre el tejido vaginal subyacente. Debe evitar doblar o torcer el cuerpo y las tiras. Puede ser necesario recortar el cuerpo del implante de malla según las dimensiones vaginales o la cantidad de disección lateral. El epitelio vaginal puede recortarse, pero debe evitarse la eliminación excesiva. Cierre el epitelio sobre el implante de malla sin usar suturas entrelazadas (como se describe a continuación; refiérase a la figura 8E). En la figura 8F se ilustra la colocación final del implante de malla en el compartimento anterior.

NOTA: asegúrese de lograr la hemostasia antes y durante el cierre de las incisiones vaginales.

Cierre las incisiones vaginales sin suturas entrelazadas o en forma de octos para evitar la desvascularización del epitelio vaginal a lo largo de las líneas de incisión y reducir la tensión de la malla. Preferentemente, el epitelio debe cerrarse en dos capas para obtener una línea de sutura relativamente gruesa en el lugar de la incisión vaginal. Cierre la capa más profunda usando puntadas subepiteliales continuas no entrelazadas con sutura del tipo MONOCRYL 2-0 o sutura antibacteriana MONOCRYL™ Plus 2-0 (poliglicaprona 23). A continuación, cierre el epitelio con puntadas tipo colchón continuas de eversion no entrelazadas, usando sutura del tipo Coated VICRYL 2-0 o sutura antibacteriana Coated VICRYL™ Plus 2-0 (poliglicatina 910). **NOTA: coloque el implante de malla en los dos tercios superiores de la vagina, con cuidado de recortar el implante de malla si sobrepasa la superficie.** Si aún no se ha hecho, se recomienda realizar una cistoscopia para descartar lesiones en el tracto urinario.

Como alternativa, puede realizarse un cierre de la pared vaginal de una sola capa utilizando puntadas tipo colchón continuas de eversion no entrelazadas o puntadas interrumpidas con sutura del tipo Coated VICRYL 2-0 o Coated VICRYL Plus 2-0.

Reparación vaginal posterior

Cuando sólo se requiere el refuerzo de la pared vaginal posterior, utilice únicamente el sistema de reparación del suelo pélvico posterior GYNECARE PROSIMA. Este contiene un implante de malla y un insertador posterior especialmente diseñado para utilizar en una reparación vaginal posterior. Una vez realizadas las incisiones y disecciones vaginales requeridas, cree los canales para el tejido en el compartimento posterior para colocar las tiras de implante de malla. **NOTA: el insertador posterior no se debe utilizar para diseccionar tejido.**

Disección vaginal y del canal posterior

Diseque el epitelio vaginal posterior del tejido prerrectal. Al igual que con la pared vaginal anterior, debe diseccionar el espesor completo de la pared vaginal posterior. Para facilitar este procedimiento debe utilizarse hidrodissección subepitelial. Continúe la disección lateralmente a cada lado de los músculos elevadores del ano a la altura de la espina isquial. Después, continúe la disección a través de cada uno de los pilares rectales y sobre cada ligamento sacroespinoso, pero no a través de ellos, creando canales en los que se colocarán las tiras del implante de malla. Refiérase a la figura 9A.

El tratamiento de un enterocele pre-existente es opcional, pero si se realiza, puede llevarse a cabo en esta etapa según la técnica preferida del cirujano.

Si la cavidad peritoneal se abre durante la disección anterior o posterior, debe cerrarse antes de colocar la malla.

Colocación del implante de malla posterior

No se requiere el plegue del tejido prerrectal. No obstante, si se realiza el plegue del tejido prerrectal, sólo debe plegarse la parte central del tejido prerrectal para que el área diseccionada no sea demasiado estrecha. Coloque el implante de malla sobre el tejido prerrectal de forma tal que los bolsillos de las tiras queden mirando hacia arriba. Si debe fijarse, debe hacerse en este momento del procedimiento con sutura del tipo MONOCRYL 2-0 o Coated VICRYL 2-0 en el ápice de la vagina, pasando las puntadas por la lengüeta apical del implante de malla. Las puntadas pueden atarse en este momento o una vez colocadas las tiras. La fijación del surco distal del implante de malla es opcional y puede hacerse con sutura del tipo MONOCRYL 2-0 o Coated VICRYL 2-0.

Usando el insertador posterior, coloque las tiras de implante de malla dentro de cada canal derecho e izquierdo creado mediante la disección hacia cada ligamento sacroespinoso (según se describe más arriba). Sujete el insertador posterior usando una guía o portaguaja rectos, como muestra la figura 9B. **NOTA: coloque la punta de la guía o portaguaja dentro del extremo estriado recto del insertador posterior.** Asegúrese de que el insertador posterior conectado está alineado con el mango de la guía o portaguaja. Inserte la punta del insertador posterior en el bolsillo de la tira del lado derecho de la paciente (refiérase a la figura 9B). A continuación, dirija el insertador posterior, con la tira cargada, hacia el interior del canal de tejido previamente creado (refiérase a la figura 9C) con el mango de la guía o portaguaja en posición vertical. A continuación, inserte en el canal la tira en toda su longitud de modo tal que la base de la tira llegue al límite superior de la disección fascial. **NOTA: inserte la primera tira completamente. Si quita el insertador antes de colocar la tira del implante de malla en el lugar deseado, deberá retirar la tira y volver a cargarla e insertarla. NOTA: tenga cuidado de no introducirlo de forma demasiado profunda para evitar dañar estructuras tisulares críticas. NOTA: si siente resistencia durante la inserción de la tira, determine la causa antes de continuar. Si sigue haciendo avanzar el insertador a pesar de la resistencia, puede dañar el implante de malla o introducirlo de forma excesiva, lo cual puede dañar las estructuras tisulares críticas.** Retire el insertador posterior siguiendo el mismo recorrido de la inserción dejando la tira en el canal. Las tiras mantienen apoyados los ligamentos sacroespinosos pero no los penetran. No coloque suturas en los ligamentos sacroespinosos. Repita el procedimiento del lado izquierdo de la paciente con la segunda tira. La figura 9D muestra ambas tiras colocadas. **NOTA: durante la colocación de la segunda tira tenga cuidado de evitar el movimiento del implante de malla y compruebe que NO está torcido.**

Posicione el cuerpo del implante de malla de forma holgada sobre la fascia vaginal subyacente. Evite doblar o torcer el cuerpo del implante de malla y las tiras. Puede ser necesario recortar el cuerpo del implante de malla según las dimensiones vaginales o la cantidad de disección lateral. El epitelio de la pared vaginal posterior puede recortarse pero debe evitarse su eliminación excesiva. Cierre el epitelio de la pared vaginal posterior sobre el implante de malla sin suturas entrelazadas (como se describe a continuación). En la figura 9E se ilustra la colocación final del implante de malla en el compartimento posterior.

NOTA: asegúrese de lograr la hemostasia antes y durante el cierre de las incisiones vaginales.

Cerre las incisiones vaginales sin suturas entrelazadas o en forma de ochos para evitar la desvascularización del epitelio vaginal a lo largo de las líneas de incisión y reducir la erosión de la malla. Preferentemente, cierre el epitelio en dos capas para obtener una línea de sutura relativamente gruesa en el lugar de la incisión vaginal. Cierre la capa más profunda usando puntadas subepiteliales continuas no entrelazadas con sutura del tipo MONOCRYL 2-0 o sutura antibacteriana MONOCRYL Plus 2-0. A continuación, cierre el epitelio con puntadas tipo colchón continuas de eversion no entrelazadas, usando sutura del tipo Coated VICRYL 2-0 o Coated VICRYL Plus 2-0. **NOTA: coloque el implante de malla en los dos tercios superiores de la vagina, con cuidado de recortar el implante de malla si sobrepasa esa altura.** Si aún no se ha hecho, se recomienda realizar una cistoscopia para descartar lesiones en el recto.

Como alternativa, puede realizarse el cierre de la pared vaginal con una sola capa utilizando puntadas tipo colchón continuas de eversion no entrelazadas de sutura del tipo Coated VICRYL 2-0 o Coated VICRYL Plus 2-0.

Reparación vaginal anterior y posterior combinada

Cuando se necesita el refuerzo de la pared vaginal tanto anterior como posterior, se utiliza el sistema de reparación del suelo pélvico combinado GYNECARE PROSIMA. Este contiene dos implantes de malla idénticos: uno para la reparación vaginal anterior y el segundo para la reparación vaginal posterior. Utilice únicamente el insertador anterior curvo para una reparación anterior y el insertador posterior recto para una reparación posterior. Realice las reparaciones vaginales anteriores y posteriores según se describe más arriba. Se recomienda realizar primero la reparación vaginal anterior. La colocación definitiva de los implantes de malla en los compartimentos anterior y posterior se ilustra en la figura 10. Al finalizar la cirugía, se recomienda realizar una cistoscopia para descartar lesiones en el tracto urinario. Se requiere un examen rectal digital para descartar lesiones en el recto.

Uso del sistema GYNECARE PROSIMA con preservación del útero (histeropexia)

Si se conserva el útero prolapso, la lengüeta apical del implante de malla debe fijarse al cuello uterino. La fijación del implante de malla sobre el cuello uterino debe realizarse a la altura del anillo pubocervical cuando se coloca durante la reparación vaginal anterior o posterior.

Cuando se conserva el útero durante una reparación vaginal anterior el anillo pubocervical queda expuesto durante la disección vaginal anterior. Coloque una sutura PROLENE 2-0 firmemente en el aspecto anterior del anillo pubocervical. Esta sutura también se coloca a través de la lengüeta apical del implante de malla. La sutura PROLENE en la lengüeta se ata una vez que las tiras de implante de malla están en su lugar. De esta manera se fija el implante de malla a la superficie anterior del cuello uterino a la altura del anillo pubocervical y asegura que el implante se dilate con la vagina cuando se posiciona el VSD de forma adecuada.

En la reparación posterior, fije el implante de malla al cuello uterino posterior a la altura del anillo pubocervical o por encima de él. El fondo de saco puede abrirse durante la fijación del implante de malla al cuello uterino. Cierre el peritoneo del fondo de saco por encima de esta sutura para evitar que los intestinos se adhieran al implante de malla. Si el cirujano decide no abrir el fondo de saco, el anillo pubocervical queda expuesto durante la disección vaginal posterior. Se coloca una sutura PROLENE 2-0 firmemente en el aspecto posterior del anillo pubocervical. Esta sutura también se coloca a través de la lengüeta apical del implante de malla. La sutura PROLENE se ata una vez que las tiras de implante de malla están en su lugar. De esta manera se fija el implante de malla a la superficie posterior del cuello uterino a la altura del anillo pubocervical.

Cuando se utilizan para reparaciones vaginales anteriores y posteriores, los implantes de malla deben fijarse a los aspectos anteriores y posteriores del cuello uterino según se describe más arriba (refiérase a la figura 11).

Higiene del implante de malla

Durante la cirugía, irrigue las heridas vaginales con solución salina. El implante de malla debe manipularse lo menos posible y debe higienizarse la malla de forma adecuada.

Colocación del VSD y del balón

Al finalizar la cirugía, coloque en la vagina un VSD del tamaño adecuado con un balón y suturelo para evitar que se salga de su lugar. El VSD puede tener 3 tamaños diferentes (pequeño, mediano y grande) y puede ser ajustado por el cirujano según la longitud de la vagina de la paciente como se indica a continuación.

Ajuste y recorte del VSD

El VSD se suministra en su tamaño más grande. Determine el tamaño apropiado para la paciente usando el VSD mismo. Para ello, coloque el VSD de tamaño grande en la vagina entre el ápice dilatado y el anillo himenal. Para introducir el VSD en la vagina, sujételo por el punto más ancho y dóblelo a lo largo del eje longitudinal con el balón hacia arriba (refiérase a la figura 12). Introduzca primero el punto más ancho del VSD de forma tal que los orificios de la sutura queden ubicados exactamente sobre el anillo himenal. **NOTA: no retire ni dañe el balón al ajustar el tamaño del VSD.** Se obtiene el tamaño adecuado cuando el VSD entra cómodamente en los dos tercios superiores de la vagina dilatada con el extremo distal y los ojos de sutura a 1 cm sobre el anillo himenal (refiérase a la figura 13).

Si el tamaño grande entra cómodamente, no es necesario modificar el VSD. Si se requiere el tamaño mediano, elimine la sección más superior recortándola cuidadosamente con las puntas de un par de tijeras Mayo curvas para cortar trozos pequeños y asegurar un borde de corte liso. Deben tomarse las precauciones necesarias para reducir al mínimo la cantidad de material que queda en las áreas de corte. **NOTA: es importante ajustar el VSD con mucho cuidado. Una vez que el VSD se corta no se puede agrandar y las secciones de corte no se pueden volver a fijar.** Haga el balón a un lado mientras recorta el VSD (refiérase a la figura 14). **Deben tomarse las precauciones necesarias para evitar dañar el balón al recortar el VSD.**

Si el tamaño mediano entra cómodamente, no es necesario realizar recortes adicionales. Si se requiere el tamaño pequeño, elimine la sección restante como se indica más arriba. Haga el balón a un lado mientras recorta el VSD para evitar dañarlo.

Una vez que se haya ajustado debidamente el tamaño del VSD y repositionado el balón, puede introducirse el conjunto en la vagina de la paciente. **NOTA: para reducir al mínimo el riesgo de perforación del balón, no utilice ningún instrumento para facilitar la inserción del VSD o del balón.** Si el balón se daña, retirelo del VSD y rellene la cavidad vaginal con gasa.

Una vez debidamente posicionado el conjunto en los dos tercios superiores de la vagina dilatada de la paciente, fije el VSD en su lugar con una sola lazada de sutura a través de cada ojo de sutura del VSD y dentro del epitelio de la pared vaginal posterior, de forma lateral y sobre el himen a cada lado, como muestra la figura 15, en las posiciones 4 y 8 horas.

A continuación, ate las suturas derecha e izquierda en ese orden, manteniendo el VSD firme en su lugar dentro de la vagina. **NOTA: tome las precauciones necesarias para no perforar el balón cuando se sutura el VSD en su lugar.** Se recomienda usar sutura absorbible del tipo Coated VICRYL 2-0 o equivalente para esta aplicación.

Inflado del balón

Una vez suturado el VSD en su lugar, fije la jeringa de 50 ml suministrada sobre la válvula del balón girándola. **NOTA: después de colocar el VSD, se requiere un catéter para evitar la retención urinaria.** Después de inflar con un pequeño volumen de aire ambiente (refiérase a la figura 16), palpe toda la longitud del balón con un dedo para asegurarse de que se ha desplegado y se ha adherido a toda la vagina. Una vez comprobado esto, retire el dedo y continúe inflando el balón al máximo hasta que solo pueda entrar cómodamente la punta de un dedo en el introitus entre el balón y la pared vaginal. Se recomienda estabilizar el VSD durante el inflado. El balón inflado sirve para mantener apoyado el implante de malla a la pared vaginal. El volumen de aire requerido para inflar el balón lo suficiente variará de una paciente a otra. **NOTA: el volumen de inflado máximo del balón no debe exceder 90 ml.** Una vez inflado lo suficiente, separe la jeringa de la válvula girándola. La línea de inflado del balón debe extenderse hacia afuera de la vagina para fijarse al muslo de la paciente. La tapa debe fijarse a la válvula del balón para asegurarse de que éste mantenga el nivel de aire deseado (refiérase a la figura 7). **NOTA: no ajuste la tapa demasiado.** En caso de que sea necesario, el balón puede ajustarse después usando una jeringa estándar para aumentar o reducir el volumen de aire en su interior. El balón puede palparse o inspeccionarse visualmente en cualquier momento para asegurarse de que se ha mantenido lo suficientemente inflado. **NOTA: a medida que la paciente se mueve, el balón se acomoda en la cavidad vaginal y puede parecer que su presión aumenta o baja. Esto es normal.**

NOTA: no separe el balón del VSD antes de utilizarlo.

NOTA: no infle el balón antes de introducirlo en la vagina.

NOTA: una vez inflado el balón, si los ojos de sutura del VSD se han movido más de 1 cm sobre el anillo himenal o si hay una tensión excesiva sobre las suturas de los ojos, reduzca la presión sobre el balón y, si es necesario, vuelva a posicionar o ajustar el tamaño del VSD.

NOTA: si observa algún orificio en el balón, o si detecta una pérdida o el balón no se mantiene dilatado después de inflarlo, NO lo utilice. Retirelo del VSD y deséchelo de forma adecuada. Utilice relleno de gasa estándar en lugar del balón.

NOTA: si el tapón conector del balón se desprende del VSD, vuelva a enpujarlo a su lugar.

NOTA: no fije la línea de inflado del balón en la vagina.

NOTA: a fin de evitar daños, no aplique nunca fuerzas de doblado, tensión o torsión extremas a la línea de inflado.

NOTA: no aplique relleno de gasa en presencia de un balón.

Retirada del balón del VSD

Usando una jeringa estándar, desinifle completamente el balón 1 día después de la cirugía y retirelo, dejando el VSD en su lugar. **NOTA: no deje el balón dentro de la vagina durante más de 1 día.**

1) Retire la tapa de la válvula del balón.

2) Conecte una jeringa estándar de 50 ml (o más grande) a la válvula del balón y desinifle totalmente (refiérase a la figura 17). Es importante que desinifle completamente el balón antes de intentar retirarlo del VSD. **NOTA: si el balón está totalmente desinflado, el émbolo de la jeringa retrocederá una vez eliminado todo el aire.**

3) Retire la jeringa.

4) A continuación, puede separarse el balón del VSD y retirarse de la paciente tirando suavemente de él en dirección caudal sobre la línea de inflado en un punto cercano al tapón conector del balón mientras se aplica una contracción suave sobre el extremo distal del VSD con un dedo. Refiérase a la figura 18.

NOTA: no retraiga el balón a menos que esté totalmente desinflado y no sienta ninguna resistencia. Si siente resistencia, determine la causa antes de continuar. Si sigue haciendo avanzar o retroceder el balón a pesar de la resistencia, puede hacer que el VSD se mueva y/o causar traumatismos en el tejido en la cavidad vaginal. Para asegurarse de que el balón está totalmente desinflado, vuelva a conectar la jeringa y elimine todo el aire antes de continuar retirándolo.

Retirada del VSD de la paciente

Retire el VSD de la paciente, aproximadamente de 3 a 4 semanas después de la cirugía, una vez que se haya producido una cicatrización suficiente. Para entonces, es posible que las suturas absorbibles se hayan disuelto o hayan perdido suficiente resistencia a la tracción para retirar el VSD fácilmente sin que la sutura presente resistencia. **NOTA: puede ser necesario cortar ambas suturas para retirar el VSD. NOTA: no deje el VSD dentro de la vagina durante más de 4 semanas.** Retire las suturas de fijación del VSD restantes. Retire manualmente el VSD del conducto vaginal, como ilustra la figura 19.

Cuidado perioperatorio

Pueden administrarse a las pacientes antibióticos profilácticos según la práctica habitual del cirujano. Los antibióticos pueden continuar administrándose después de la operación según la preferencia del cirujano. Puede usarse profilaxis tromboembólica.

El cirujano debe explicar que el propósito del VSD, que queda en la vagina hasta cuatro semanas después de la cirugía, es servir de apoyo a la vagina contra la malla durante el periodo de cicatrización. Debe indicarse a la paciente que el VSD se extraerá durante un control post-operatorio, aproximadamente 4 semanas después de la cirugía. También debe indicarse a la paciente que puede experimentar pérdidas vaginales post-operatorias y que el VSD puede desplazarse ligeramente hacia abajo. Si la paciente siente que el VSD se ha desplazado hacia abajo, puede empujarlo suavemente hacia arriba a una posición más cómoda. No obstante, si el VSD está causando demasiado malestar, debe indicarse a la paciente que se ponga en contacto con su médico.

Una vez que ha recibido el alta, debe indicarse a la paciente que evite las actividades intensas durante un periodo de 3 a 4 semanas. Para entonces, los tejidos pélvicos se habrán incorporado al implante de malla y la paciente podrá reanudar sus actividades cotidianas habituales. Debe indicarse a la paciente que evite las relaciones sexuales durante al menos 6 semanas después de la cirugía. Puede recomendarse la realización de ejercicios del suelo pélvico en cualquier momento después de la cirugía.

RENDIMIENTO

Los estudios realizados en animales demuestran que la implantación de la malla GYNECARE GYNEMESH PS provoca una reacción inflamatoria pasajera de mínima a leve, seguida por la deposición de una capa fibrosa delgada de tejido capaz de crecer entre los intersticios de la malla y, de esta manera, incorporarla al tejido adyacente. La malla se mantiene blanda y maleable y la cicatrización normal de la herida no se ve afectada de forma notoria. El material no es absorbido ni sometido a degradación o debilitamiento por la acción de las enzimas de los tejidos.

CONTRAINDICACIONES

- Cuando la malla GYNECARE GYNEMESH PS se utiliza en bebés, niños, mujeres embarazadas o mujeres que tienen pensado tener hijos en el futuro, el cirujano debe ser consciente de que este producto no se estirará de forma significativa a medida que crece el paciente.
- El sistema GYNECARE PROSIMA no debe realizarse en pacientes embarazadas o con infecciones purulentas o cánceres de la vagina, cuello uterino o útero.

ADVERTENCIAS Y PRECAUCIONES

- Antes de utilizar los sistemas GYNECARE PROSIMA, se recomienda a los usuarios familiarizarse con los procedimientos y técnicas quirúrgicas para la reparación del suelo pélvico y mallas no absorbibles.
- El uso del sistema GYNECARE PROSIMA no se ha evaluado totalmente en pacientes con prolapso del órgano pélvico en etapa IV. Por lo tanto, no se recomienda su uso en estas pacientes.
- Deben seguirse las prácticas quirúrgicas aceptables para el sistema GYNECARE PROSIMA, así como para el tratamiento de heridas infectadas o contaminadas.
- No utilice el sistema GYNECARE PROSIMA si cree que el sitio quirúrgico puede estar infectado o contaminado. Si el implante de malla o el conjunto de balón VSD se utiliza en áreas contaminadas, sólo debe usarse teniendo en cuenta que cualquier infección resultante podrá requerir su extracción.
- Debe recomendarse a la paciente que, después de la operación, se abstenga de levantar objetos pesados y/o hacer ejercicio (por ejemplo, ir en bicicleta o correr) durante 3 a 4 semanas y que se abstenga de tener relaciones sexuales durante 6 semanas o hasta que el médico determine que puede reanudar sus actividades normales.
- No deje el VSD dentro de la vagina durante más de 4 semanas.
- No deje el balón dentro de la vagina durante más de 1 día.
- Los componentes del sistema GYNECARE PROSIMA no están diseñados para ser utilizados con dispositivos distintos de los mencionados en este manual.
- Evite ejercer una tensión excesiva sobre el implante de malla durante su manipulación.
- Utilice los sistemas GYNECARE PROSIMA con cuidado y prestando atención a la anatomía de la paciente para evitar dañar los vasos, los nervios, la vejiga y los intestinos y perforar la pared vaginal. El uso correcto de los componentes del sistema GYNECARE PROSIMA reducirá al mínimo los riesgos.
- Inñe el balón únicamente con aire ambiente.
- El palpado confirmará que el balón no contiene ninguna pérdida de aire una vez inflado. Si el balón se desinfla totalmente, puede perder eficacia.
- La pared del balón es delgada para poder obtener los efectos deseados. Las perforaciones, cortes, muescas, aplastamiento o aplicación de tensiones excesivas pueden hacer que el balón se desinfle. El balón puede perforarse fácilmente con una aguja o escalpelo o romperse al manipularlo con un instrumento romo. Proceda con precaución durante su manipulación para evitar que eso ocurra. Los balones dañados no deben usarse. Retírelos y rellene la vagina con gasa.
- El nivel de inflado máximo del balón es de 90 ml. No lo infle excesivamente ya que puede producir molestias a la paciente, necrosis tisular, abertura de la herida vaginal después de la cirugía o imposibilidad de evacuar.
- No utilice los sistemas GYNECARE PROSIMA en pacientes sometidas a terapia anticoagulante.
- Puede producirse hemorragia después de la intervención. Observe cualquier síntoma o indicio antes de dar de alta a la paciente.
- Debe indicarse a la paciente que llame al cirujano inmediatamente en caso de dolor inusual, hemorragia u otros problemas.
- Aunque es poco probable que se produzcan lesiones en la vejiga con esta técnica, debe realizarse una distoscopia.
- Aunque es poco probable que se produzcan lesiones en el recto con esta técnica, se recomienda realizar un examen digital.
- No fije el implante de malla GYNECARE GYNEMESH PS con grapas, clips o pinzas de ningún tipo, ya que se podría causar algún daño mecánico a la malla.
- El implante de malla no debe estar presente en el tercio inferior de la vagina. Si es necesario, recorte el implante de malla hasta la unión del tercio inferior y medio de la pared vaginal.
- Pueden administrarse antibióticos profilácticos según la práctica habitual del cirujano.

REACCIONES ADVERSAS

- Las posibles reacciones adversas son las típicamente asociadas con materiales implantables quirúrgicos e incluyen potenciamiento de infecciones, inflamación, formación de adherencias, formación de fistulas, erosión, extrusión y heridas que producen contracción del implante.
- Las reacciones adversas potenciales son las típicamente asociadas con los procedimientos de reparación del prolapso del órgano pélvico, como dolor en las relaciones sexuales y dolor pélvico. Pueden resolverse solas con el tiempo.
- Pueden producirse laceraciones o perforaciones en vasos, nervios, la vejiga, la uretra o los intestinos durante la disección o la colocación de la malla y pueden necesitar reparación quirúrgica.
- La disección para los procedimientos de reparación del suelo pélvico puede dificultar la evacuación normal durante una cantidad de tiempo variable.

ESTERILIDAD

Los sistemas GYNECARE PROSIMA están esterilizados con óxido de etileno. NO REESTERILICE ninguna parte del sistema GYNECARE PROSIMA. NO REUTILICE ninguna parte del sistema GYNECARE PROSIMA. La reutilización de este dispositivo (o partes del mismo) puede crear un riesgo de degradación del producto y contaminación cruzada, lo que puede llevar a infecciones o transmisión de patógenos sanguíneos a pacientes y usuarios. No utilizar si el envase está abierto o dañado. Desechar todos los componentes abiertos del sistema GYNECARE PROSIMA no utilizados.








ELIMINACIÓN

Deseche los componentes y envases del sistema GYNECARE PROSIMA según las normas y procedimientos utilizados en su centro para materiales y desechos biopeligrosos.

ALMACENAMIENTO

Condiciones de almacenamiento recomendadas: temperatura ambiente y humedad relativa controladas (aproximadamente 25 °C, 60 % humedad relativa), alejado de la humedad y el calor directo. No usar después de la fecha de caducidad.

Símbolos utilizados en las etiquetas

 0086 Marca CE y número de identificación del organismo notificado. Este producto cumple los requisitos esenciales de la directiva sobre productos sanitarios 93/42/CEE.	 Fabricante
 LOT	Número de lote
	Utilizar antes del mes y año
	Un solo uso/No reesterilizar
	Ver las instrucciones de uso
	Método de esterilización: — óxido de etileno



System för reparation av främre delen av bäckenbotten
System för reparation av bakre delen av bäckenbotten
System för kombinerad reparation av bäckenbotten

SVENSKA

Läs noga igenom all information.

Om dessa anvisningar inte följs, kan det resultera i att instrumenten inte fungerar korrekt och även medföra att skada uppstår.

OBS! Enligt amerikansk federal lag är försäljning av denna anordning förbjuden annat än genom läkare eller på läkares ordination.

Utbildning i hur man använder GYNECARE PROSIMA™ system för reparation av bäckenbotten rekommenderas och kan ordnas. Kontakta företagets försäljningsrepresentant för att planera utbildning.

INDIKATIONER

GYNECARE PROSIMA system för reparation av bäckenbotten, genom placering av GYNECARE GYNEMESH™ PS icke resorberbart mjukt PROLENE™ nätmplantat, är indikerat för vävnadsförstärkning och långvarig stabilisering av fasciastrukturer i bäckenbotten, antingen som mekaniskt stöd eller som övergångsmaterial vid fasciaskada. Systemen ger stöd åt vaginalkanalen i läkningsprocessen efter kirurgisk reparation av vaginalväggsprolaps samtidigt som de stöder nätmplantatets placeringar.

BESKRIVNING

GYNECARE PROSIMA system för reparation av främre och bakre och kombinerad reparation av bäckenbotten består av tillknypta GYNECARE GYNEMESH PS nätmplantat och instrument för att underlätta implantatplacering och stöd efter operation (se figur 1). I följande tabell finns en sammansättning av de komponenter som ingår i respektive system:

SYSTEM FÖR REPARATION AV BÄCKENBOTTEN	KOMponenter (se figur 1)				
	Nätimplantat i hållare (A)	Vaginalstöd – Ballonggenhet (B&C)	Främre införare (D)	Bakre införare (E)	Injektionsspruta (F)
Främre	1	1	1		1
Bakre	1	1		1	1
Kombinerad	2	1	1	1	1

Tabell 1 – Komponenter i GYNECARE PROSIMA system för reparation av bäckenbotten

GYNECARE GYNEMESH PS

GYNECARE GYNEMESH PS är ett nät tillverkat av sammanvävda filament av strängsprutad polypropen med en sammansättning som är identisk med PROLENE™ polypropylensutur (ETHICON, INC.). Detta material har vid användning som suturmateriell rapporterats vara icke-reaktivt och behålla sin hållfasthet under obegränsad tid vid klinisk användning. Nätet är utomordentligt starkt, hållbart och kirurgiskt anpassningsbart och samtidigt tillräckligt poröst för att möjliggöra nödvändig vävnadsväxt. Bå PROLENE- suturmateriell har vävts in för att ge kontrasterande ränder i nätet. Nätet är gjort av monofilamentfiber med reducerad diameter, vävda i en unik design som ger ett nät som är ca 50 procent mer flexibelt än PROLENE™ polypropylennät av standardtyp. Nätet är tillverkat enligt en process som lämnar sammanväg fiberkonstruktion vilket ger elasticitet i båda riktningarna. Tack vare denna konstruktion kan nätet klippas till vilken form och storlek som helst utan att fransas upp. Denna tvåvägselasticitet gör att nätet kan anpassa sig till de varierande påfrestningar som uppstår i kroppen.

Nätimplantat

Nätimplantat görs av GYNECARE GYNEMESH PS. Nätimplantaten är tillknypta i en Y-form för reparation av defekter i främre, bakre och/eller apikala delen av vagina. Se figur 2. Nätimplantatet har 2 remmar och en central huvuddel. Det finns en apikal fick på den proximala änden som fästs med sutur för att minimera nätimplantatets rörelse under placeringen av remmarna. Det finns en distal skära på den distala änden för att underlätta inriktningen av nätimplantatet. Nätimplantatets remmar har tillknypta fickor för att implantatet ska kunna placeras med införarna. Nätimplantatet levereras i en implantathållare som består av obelagd Tyvek® och en genomskinlig plastfilm, som är utformad för att låta ta av från nätimplantatet.

Främre införare

Den främre införaren är ett instrument för enpatientbruk som har utformats för att underlätta införingen av nätimplantatets remmar i de främre tidigare dissekerade vävnadskanalerna. **ANM: Den främre införaren är inte avsedd för dissektion av vävnad.** Den främre införaren har utformats så att den är kompatibel med nätimplantatets fickor för att remmarna ska kunna placeras på patientens båda sidor i de främre rummen. Se figurerna 3 och 4.

Bakre införare

Den bakre införaren är ett instrument för enpatientbruk som har utformats för att underlätta införingen av nätimplantatets remmar i de bakre tidigare dissekerade vävnadskanalerna. **ANM: Den bakre införaren är inte avsedd för dissektion av vävnad.** En standardhöllare fästs vid den bakre införaren och stabiliserar för att få kontrollerad införing. Den bakre införaren har utformats så att den är kompatibel med nätimplantatets fickor för att remmarna ska kunna placeras på patientens båda sidor i de bakre facken. Se figur 5.

Vaginalstöd (VSD)

VSD är en enhet för enpatientbruk som är utformad för att efter operation ge stöd för vävnaden i vagina efter placeringen av nätimplantatet och stängning av vaginalincisioner. Den apikala delen av VSD är bredast och består av justerbara sektioner. Efter den första dimensioneringen i patienten, kan VSD justeras så att den passar patientens anatomi genom avklippning av särskilda apikala sektioner. VSD placeras i övre 2/3 av patientens vagina i 3 till 4 veckor och avlägsnas sen. Se figur 6.

Ballong

Ballongen är avsedd för enpatientbruk och är utformad för att ersätta gasvävsförband i vagina efter operation. Ballongens volym kan anpassas för att fylla vaginalkanalen och stödja nätimplantatet mot vaginalväggen. Ballongen är fäst på VSD. Figur 7 visar den ofyllda ballongen utan VSD. Ballongen sitter kvar i patienten i upp till en dag.

Injektionsspruta

En 50 ml injektionsspruta tillhandahålls för att fylla ballongen.

AVSNITT 1: PRINCIPERNA FÖR ATT ANVÄNDA GYNECARE PROSIMA-SYSTEMET

En reparation av bäckenbotten med användning av GYNECARE PROSIMA-systemet ska ge en anatometrisk, hållbar och standardiserad reparation av prolaps av bäckenbottenorgan. Beroende på var prolapsen är och kirurgens preferenser, kan antingen främre eller bakre reparation väljas. Hysterektomi eller bibehållande av livmodern kan kombineras med användning av GYNECARE PROSIMA-systemet. Om så indikeras kan en reparation av perineum eller en suburetral synga för behandling av ansträngningsinkontinens göras samtidigt när GYNECARE PROSIMA-systemet används. En retropubisk eller transobturator suburetral synga kan användas.

Prolapsreparation erhålls genom placering av 1 eller 2 nätimplantat via vagina. Efter operationen placeras en VSD med en upplösbar ballong i vagina för dimensionering och VSD fästs med sutur på plats, och stödjer på så vis vagina och nätimplantatet under vävnadsväxt. När ballongen fyllts, ersätter den traditionella gasvävsförband genom att fylla vaginalhålligheten och stödja nätimplantatet mot vagina. Dagen efter operationen töms ballongen och avlägsnas från vagina utan att lossa VSD. VSD:n stannar på plats i maximalt 4 veckor efter operationen, under vävnadsväxten i nätimplantatet.

AVSNITT 2: GRUNDEN TILL GYNECARE PROSIMA-SYSTEMET

Efter konventionell kirurgi för prolaps av organ i bäckenbotten, utsätts reparerad vävnad för ökad intraabdominellt tryck när patienten rör sig, hostar, kräks och anstränger sig vid tarmtömning. Dessa öknings i intraabdominellt tryck kan påverka läkningen av vaginalreparation negativt och kan leda till att operationen misslyckas och att ny prolaps utvecklas. Genom att förstärka vaginalreparationen med nätimplantat och stödja vagina med VSD i 3 till 4 veckor efter operationen, är GYNECARE PROSIMA-systemet utformat för att minska risken för misslyckad operation och återkommande prolaps.

Under reparation av främre delen av vaginans ska nätimplantatets huvuddel placeras utan spänning mellan urinblåsan och vaginas övre 2/3 och sträcka sig lateralt nivå med arcus tendineus fascia pelvis (ATFP). Vid reparation av bakre delen av vaginans ska nätimplantatets huvuddel placeras utan spänning mellan rektum och vaginas övre 2/3, och inpassas lateralt över levator ani-muskulerna. Den apikala delen av nätimplantatets huvuddel ska nå vaginas apex. Framåt kan nätimplantatet fästas vid prevexilat vävnad eller cervix. Bakåt kan nätimplantatet fästas vid prerrektal vävnad eller cervix.

VSD stödjer vaginalvävnaden efter operation och underlättar att nätimplantatet stöds mot vaginalväggen tills vävnadsväxt sker. Vävnadsväxt genom nätimplantatet sker under 3 till 4 veckor efter operation. Genom att använda GYNECARE PROSIMA-systemet undviks behovet av dissektion utanför bäckenhållan och passage av sutur och instrument genom obturator foramen och sakrospinalligament, vilket gör operationen enklare att genomföra.

Hysterektomi

Kirurgens preferenser och patientens behov bestämmer om hysterektomi krävs. När en hysterektomi utförs, rekommenderas slutning av peritoneums cul-de-sac för att undvika att nätimplantatet kommer i kontakt med tarmar. En "T"-smittslutning ska undvikas eftersom det kan öka risken för nätexponering. När vaginalhysterektomi utförs tillsammans med antingen främre eller bakre eller kombinerad reparation, ska hysterektomisnittet slutas på tvären och reparationssnittet läggas så att de inte kommer i kontakt med det slutna hysterektomisnittet. Detta görs för att undvika att det blir ett "T"-snitt.

Bibehållande av livmodern

GYNECARE PROSIMA-systemet är lämpligt i situationer när kirurgen eller patienten väljer att bibehålla livmodern.

Vaginalincisioner

Vaginalincisioner vid användning av GYNECARE PROSIMA-systemet är desamma som de som används av kirurgen vid rutinvaginalreparation. Incisioner ska göras genom hela vaginalväggens djup för att minska risken för nätexponering.

Nätimplantatplacering

Nätimplantatet hålls på plats av VSD:n tills vävnadsväxt sker. Därför är det inte nödvändigt att sätta fäst nätimplantatets remmar. Nätimplantatets apikala del kan fästas i fascian i vaginalapex mittlinje med en sutur som 2-0 MONOCRYL™ (polyglaktin 25) eller 2-0 Coated VICRYL™ (polyglaktin 910). Vaginalepitellet ska inte fästas med sutur i nätimplantatet.

Bibehållande av vagina

Sortragnit eller resektion av för mycket vaginalsepitel ska undvikas. Viss vävnadsretraktion kan ske efter operation och minskad vaginalkapacitet kan förvärras om för mycket vaginalsepitel avlägsnas.

Tre nivåer av vaginalstöd

Tre nivåer av vaginalstöd är allmänt kända för vaginalreparation. Användning av GYNECARE PROSIMA-systemet är avsett att ge stöd på nivå I och II på följande vis:

Nivå I – Suspension och stöd (övre tredjedelen av vagina)

Den övre tredjedelen av vagina (inklusive valvet efter en hysterektomi) och livmodern stöds av 2 mekanismer. För det första ges direkt stöd för livmodern och övre vagina genom parametrium (kardinal- och uterosakralligament) och parakolpiefibror. Dessa fibrer agerar som suspensionsligament och kommer från piriformis-muskeln fascia, sakrospinallleden och laterala sakrum och går in i laterala övre tredjedelen av vagina och postero-laterala delen av cervix. För det andra ges indirekt stöd för livmodern och övre vagina genom levatorplattan som formas genom sammanslagningen av högra och vänstra levator ani-muskulerna mellan rektum och coccyx. Livmodern- och vaginalväggsprolaps sker som ett resultat av att dessa direkta och indirekta stödmekanismer inte fungerar. Detta innebär troligtvis svaghet i bäckenbottenmuskulaturen och suspensionsfibrerna i parametrium och över parakolpet. Syftet med prolapskirurgi på nivå I är att återställa direkta och indirekta stödmekanismer. GYNECARE PROSIMA-systemet använder nätimplantatets remmar för att fästa mot varje obturator internus-muskel och den överliggande fascian vid främre vaginalreparation och nätimplantatets remmar stödjer mot sakrospinalligamentet vid bakre vaginalreparation. Detta ger direkt stöd genom suspension och indirekt stöd genom att ge nätimplantatstöd till ett stort område av övre vagina och livmodern.

Nivå II – Lateral fastsättning (mittensta tredjedelen av vagina)

Mittén av vagina sitter fast lateralt och direkt vid musklerna på bäckenets sidovägg genom arcus tendineus fasciae pelvis (ATFP). På denna nivå sträcks den främre och bakre vaginalväggen mellan höger och vänster lateralfästen. På nivå II flyttar prolapspreparation till att återfåsta laterala delen av mittensta delen av vagina till musklerna i bäckenets sidovägg. Centrala defekter på mittensta vagina kräver också stöd på nivå II. Användning av GYNECARE PROSIMA-systemet i ett ingrepp återskapar vaginas laterala fästen på bäckenets sidoväggsmuskler och förstärker också centrala fascian efter vävnadsvinnet.

Nivå III – Fusion (nedre tredjedelen av vagina)

ANM: Dissektion av detta område krävs inte vid användning av GYNECARE PROSIMA-systemet.

På nivå III går den främre nedre tredjedelen av vagina ihop med perinealmembranet och uretra. Den bakre nedre tredjedelen av vagina fästs vid centrala perinealsenan och levator ani-musklerna. Vävnaderna i detta område repareras utan nålimplantat, eftersom nålimplantat inte är avsett att användas i nedre tredjedelen av vagina. GYNECARE PROSIMA-systemet är inte anpassat som stöd vid nivå III: defekter, fast de kan användas vid samtida ingrepp som perineoraf.

AVSNITT 3: BRUKSANVISNING

ANM: I detta avsnitt refereras till figurerna i början av dokumentet.

Förberedelse för operation

Kirurgi som utförs med GYNECARE PROSIMA-systemet kan utföras under allmän eller lokal anestesi, enligt kirurgens, narkosläkarens och patientens preferenser.

Patienten ska placeras i litotomi position med bakdelen lätt hängande över operationsbordets kant och med böjd höft. Enligt kirurgens önskan kan blåsan tömmas. En kateter behövs före införing av ballongen och den kan föras in vid detta tillfälle i ingreppet.

Användning av GYNECARE PROSIMA-systemet efter hysterektomi**Främre vaginalreparation**

När endast förstärkning av den främre vaginalväggen behövs, ska endast GYNECARE PROSIMA-systemet för reparation av främre bäckenbotten användas. Det innehåller 1 nålimplantat och en särskilt anpassad främre införare för användning vid främre vaginalreparation. Efter att de nödvändiga vaginalincisionerna och -dissektionerna gjorts, görs vävnadskanaler i främre rummet för placering av nålimplantatets remmar med hjälp av den främre införaren. **ANM: Den främre införaren får inte användas för vävnadsdissektion.**

Främre vaginaldissektion

Främre vaginalpetelet dissekas från blåsan. Dissekera hela vaginalväggens tjocklek. Denna dissektion bör underlättas genom subepitel hydrodissektion. Yttig dissektion av vaginalväggen eller separation av vaginalväggen i 2 lager bör undvikas. Sådan dissektion kan resultera i en väldigt tunn vaginalvägg och kan också kompromissa vaginalväggs blodförsörjning och därmed öka risken för implantatexponering. Fortsätt dissektionen lateralt mot bäckenets sidovägg och till ischialtappen.

Dissektion av främre kanalen och placering av nålimplantat

Utför dissektionen för att forma kanaler för nålimplantatets remmar först på patientens högra sida och sen på den vänstra, enligt denna bruksanvisning. Dessa kanaler formas för att placera nålimplantatet så att den distala delen av remmarna ligger platt mot bäckenets sidovägg och obturator internus-muskelns parietalfascia. För att placera remmarna, inled dissektionen med ett palpera och identifiera ischialtapparna på båda sidorna. **ANM: Alternativt kan denna dissektion startas med sax och en "push-spread"-teknik, så att saxens spetsar alltid är innanför ischialtappen.** Följ upp den initiala dissektionen med försiktig fingerdissektion till ischialtappen. Vid kontakt med ischialtappen svep pekfingeret för att skapa ett rum framför och över ischialtappen. Se figur 8A. Inriktningen på denna dissektion är vinkelrät mot bäckenets sidovägg och formar ett ungefär 2 cm brett och 3 cm högt rum. I främre dissektion ingår inte dissektion av sakrospinalligamenten. Denna dissektion formar en kanal framför och över ischialtappen och yttigare än ATFP, obturator internus-muskeln och dess parietalfascia. Upprepa samma dissektion på vänster sida.

Plikation av den prevesikala vävnaden behövs inte. Om plikation emellertid utförs, plikeras endast den centrala delen av vävnaden. På så sätt undviker man att göra det dissekerade området för smalt. Placera nålimplantatet över den prevesikala vävnaden med remmarnas fickor vända uppåt. Om fastsättning ska ske, ska det göras här i ingreppet genom att placera en sutur som 2-0 MONOCRYL eller Coated 2-0 VICRYL i vaginaapex och trå genom nålimplantatets apikala flik. Stygnet kan knytas fast nu eller när remmarna har placerats. Det är valfritt att fästa nålimplantatets distala skära och det kan göras med en sutur som 2-0 MONOCRYL eller 2-0 Coated VICRYL.

Använd den främre införaren och placera nålimplantatets remmar införda i höger och vänster kanal som formats genom dissektion framför och ovanför ischialtappen (som beskrivs ovan). **ANM: De böjda ändarna på den främre införaren är vridda åt motsatta håll och det finns pilar på varje ände som visar vilken riktning den ska placeras i.** Pilen ska peka åt patientens högra sida när du för in spetsen på den främre införaren i fickan på nålimplantatets rem (se figur 8B) på patientens högra sida. **ANM: Sträckning i motsatt riktning kan hjälpa till att hålla fickan kvar på den främre införaren.** Håll den främre införaren i vertikal position, så att den böjda delen av instrumentet är mot den bakre vaginalväggen, rikta sen in den främre införaren, med remmen fastsatt, i den redan formade vävnadskanalen (se figur 8C) tills handtaget kommer i kontakt med labia majora på motsatt sida. Detta sker genom att positionera främre införarens handtagsdel i uppåt-vertikal riktning så att den ledande kanten och fickan går mot ischialtappen. När den har positionerats, låta handtaget nedåt till nästan horisontell position, medan handtaget hålls kvar i kontakt med motsatt får. **ANM: Vid initial placering i kanalen kan det vara till hjälp om man flyttar undan urinblåsan med ett kirurgiskt standardinstrument. Om så önskas kan pekfingeret användas i kanalen för att leda den första placeringen av den främre införaren mot motsatt sidas labia majora, innan handtaget sänks.** Tryck lätt uppåt för att säkerställa att remmarnas fickor positioneras korrekt och nålimplantatets apikala del stöds mot vaginalapex. **ANM: Om du känner motstånd vid införing av remmarna, fastställ orsaken innan du fortsätter. Om du fortsätter att föra in införaren trots att du känner motstånd kan det leda till skada på nålimplantatet eller att införaren förs in för långt och skadar viktiga vävnadsstrukturer.**

För att avlägsna den främre införaren, låta tillbaka handtaget till vertikal position innan du drar ut och låt remmen vara kvar i kanalen. **ANM: För in den första remmen helt. ANM: Om den främre införaren dras ut innan nålimplantatet har nått sitt mål, måste remmen avlägsnas och föras in igen.** Upprepa detta på patientens motsatta sida genom att vända den främre införaren och föra in änden i den andra fickan med pilen pekandes åt patientens vänstra sida. Figur 8D visar när båda remmarna har placerats. **ANM: Vid placeringen av den andra remmen, var försiktig så att inte nålimplantatet flyttar sig och bekräfta att nålimplantatet INTE har vridd sig.**

Positionera nålimplantatets huvuddel löst över den underliggande vaginalvävnaden. Huvuddelen och remmarna ska inte vikas eller vridas. Nålimplantatets huvuddel kan behöva klippas till beroende på vaginas dimensioner och-mängden laterala defekter. Vaginalpetelet kan trimmas, men för avlägsnande av för mycket vaginalpetel bör undvikas. Slut

epitelet över nålimplantatet utan sammanfogande suturer (som beskrivs nedan, se figur 8E). Nålimplantatets slutliga placering i främre rummet visas i figur 8F.

ANM: Se till att hemostas uppnås före och under slutning av vaginalincisionerna.

Stäng vaginalincisionerna utan interlocksutur eller kryssutur (figure-of-eight). Detta är för att undvika devaskularisering av vaginalpetelet längs incisionen och för att minska implantatmötning. Epitelet sluts företrädesvis i 2 lager för att få en relativt tjock suturlinje på platsen för vaginalincisionen. Stäng det djupa lagret med ett kontinuerligt subepitelt icke-interlockstyggn med en sutur som 2-0 MONOCRYL eller 2-0 MONOCRYL™ Plus antibakteriell sutur (poliglekapron 25). Stäng sedan epitelet med ett icke-interlock kontinuerligt vrängt madrasstyggn, med en sutur som 2-0 Coated VICRYL eller 2-0 Coated VICRYL™ Plus (polyglaktin 910) antibakteriell sutur. **ANM: Placera nålimplantat i den övre 2/3 av vagina och se till att klippa till det om det sträcker sig utanför övre 2/3.** Om det inte redan gjorts rekommenderas cytoskop för att utesluta skada på urinvägarna.

Alternativt kan stängning av vaginalväggen göras med ett enkelt lager. Ett kontinuerligt vrängt icke-interlock madrasstyggn eller avbrutet stygn med en sutur som 2-0 Coated VICRYL eller 2-0 Coated VICRYL Plus kan användas.

Bakre vaginalreparation

När endast förstärkning av den bakre vaginalväggen behövs, använd endast GYNECARE PROSIMA-systemet för reparation av bakre bäckenbotten. Det innehåller 1 nålimplantat och en särskilt anpassad bakre införare som används vid bakre vaginalreparation. Efter att de nödvändiga vaginalincisionerna och -dissektionerna gjorts, forma vävnadskanaler i bakre rummet för att placera nålimplantatets remmar i. **ANM: Den bakre införaren får inte användas för vävnadsdissektion.**

Bakre vaginal- och kanaldissektion

Dissekera det bakre vaginalpetelet från den prerektala vävnaden. Sen med den främre vaginalväggen ska hela bakre vaginalväggs tjocklek dissekas. Denna dissektion bör underlättas genom subepitel hydrodissektion. Fortsätt dissektionen lateralt på båda sidorna om levator ani-musklerna i nivå med ischialtappen. Fortsätt sedan dissektion genom varje rektalpelare och till, men inte genom, varje sakrospinalligament, och forma kanalen som nålimplantatets remmar ska placeras i. Se figur 9A.

Behandling av preexisterande enterocele är valfri, men om den utförs kan den utföras i detta stadium enligt kirurgens valda teknik.

Om den peritoneala håligheten öppnas under antingen främre eller bakre dissektion måste den stängas innan nätet placeras.

Bakre nålimplantatplacering

Plikation av den prerektala vävnaden behövs inte. Om plikation av den prerektala vävnaden emellertid utförs, plikeras endast den centrala delen av den prerektala vävnaden. På så sätt undviker man att göra det dissekerade området för smalt. Placera nålimplantatet över den prerektala vävnaden med remmarnas fickor vända uppåt. Om fastsättning ska ske, ska det göras här i ingreppet genom att placera en sutur som 2-0 MONOCRYL eller 2-0 Coated VICRYL i vaginalapex och trå genom nålimplantatets apikala flik. Stygnet kan knytas fast nu eller när remmarna har placerats. Det är valfritt att fästa nålimplantatets distala skära och det kan göras med en sutur som 2-0 MONOCRYL eller 2-0 Coated VICRYL.

Använd den bakre införaren och placera nålimplantatets remmar införda i varje höger och vänster kanal som formats genom dissektion mot varje sakrospinalligament (som beskrivs ovan). Grip tag i den bakre införaren med en rak nålförare, som visas i figur 9B. **ANM: Placera nålförarens spets i den raka spårade änden av den bakre införaren.** Kontrollera att den anslutna bakre införaren är i linje med nålförarens handtag. För in spetsen på den bakre införaren i remmarnas fickor på patientens högra sida (se figur 9B). Rikta sen in den bakre införaren, med remmen fastsatt, i den redan formade kanalen (se figur 9C), med nålförarens handtag i upprätt position. För sedan in hela remmens längd i kanalen så att remmens bas når den fasciala dissektionens övre avgränsning. **ANM: För in den första remmen helt. Om införaren dras ut innan remmen har nått sitt mål, måste remmen avlägsnas och föras in igen. ANM: Var försiktig så att remmen inte förs in för långt och orsakar skada på viktiga vävnadsstrukturer. ANM: Om du känner motstånd vid införing av remmarna, fastställ orsaken innan du fortsätter. Om du fortsätter att föra in införaren trots att du känner motstånd kan det leda till att nålimplantatet skadas eller att införaren förs in för långt och skadar viktiga vävnadsstrukturer.** Dra tillbaka den bakre införaren längs införingssgängen och lämna kvar remmen i kanalen. Remmarna fäster vid, men tränger inte igenom, de sakrospinala ligamenten. Placera inte suturer genom de sakrospinala ligamenten. Upprepa proceduren på patientens vänstra sida med den andra remmen. Figur 9D visar när båda remmarna har placerats. **ANM: Vid placeringen av den andra remmen, var försiktig så att inte nålimplantatet rör sig och bekräfta att nålimplantatet INTE har vridd sig.**

Positionera nålimplantatets huvuddel löst över den underliggande vaginalfascian. Undvik att vika eller vrida nålimplantatets huvuddel och remmar. Nålimplantatets huvuddel kan behöva klippas till beroende på vaginas dimensioner och-mängden laterala defekter. Bakre vaginalväggsepitelet kan trimmas, men avlägsnande av för mycket vaginalpetel bör undvikas. Stäng det bakre vaginalväggsepitelet över nålimplantatet utan sammanfogande suturer (som beskrivs nedan). Nålimplantatets slutliga placering i bakre rummet visas i figur 9E.

ANM: Se till att hemostas uppnås före och under slutning av vaginalincisionerna.

Stäng vaginalincisionerna utan att använda interlocksutur eller kryssutur (figure-of-eight). Detta är för att undvika devaskularisering av vaginalpetelet längs incisionen och för att minska implantatmötning. Stäng företrädesvis epitelet i 2 lager för att få en relativt tjock suturlinje på platsen för vaginalincisionen. Stäng det djupa lagret med ett kontinuerligt subepitelt icke-interlockstyggn med suturer som 2-0 MONOCRYL eller 2-0 MONOCRYL Plus antibakteriell sutur. Stäng sen epitelet med ett icke-interlock kontinuerligt vrängt madrasstyggn, med en sutur som 2-0 Coated VICRYL eller 2-0 Coated VICRYL Plus. **ANM: Placera nålimplantat i den övre 2/3 av vagina och se till att klippa till nålimplantatet om det sträcker sig utanför övre 2/3.** Efter avslutad operation krävs en digital rektalundersökning för att utesluta rektal skada.

Alternativt kan stängning av vaginalväggen göras med ett enkelt lager. Ett kontinuerligt vrängt icke-interlock madrasstyggn eller avbrutet stygn med en sutur som 2-0 Coated VICRYL eller 2-0 Coated VICRYL Plus kan användas.

Kombinerad bakre och främre vaginalreparation

När både främre och bakre vaginalväggen behöver förstärkas används GYNECARE PROSIMA-systemet för kombinerad reparation av bäckenbotten. Detta innehåller 2 identiska nålimplantat, ett för främre vaginalreparation och ett andra för bakre vaginalreparation. Använd endast den böjda främre införaren för främre reparation och den raka bakre införaren för bakre reparation. Utför den främre och bakre vaginalreparation på det sätt som beskrivs ovan. Det rekommenderas att den främre vaginalreparationen utförs först. Nålimplantatets slutliga placering i främre och bakre rummen visas i figur 10. Efter operationen rekommenderas att en cytoskop utförs för att utesluta skada på urinvägarna. En digital rektalundersökning krävs för att utesluta rektal skada.

Användning av GYNECARE PROSIMA-systemet med bibehållande av livmodern (hysteropexi)

Om den framförelna livmodern bibehålls, ska nålimplantatets apikala flik fixeras vid cervix. Fixering av nålimplantat till cervix ska ske i nivå med den pubocervikala ringen när det placeras genom främre eller bakre vaginalreparation.

När livmoder bibehålls under främre vaginalreparation exponeras pubo-cervikalringen under främre vaginaldissektion. Placera en 2-0 PROLENE-sutur stadigt i pubo-cervikalringens främre kant. Suturen placeras också genom nätmplantatets apikala flik. PROLENE-suturen i fliken knys efter att nätmplantatets remmar är på plats. Detta säkrar nätmplantatet till cervix främre yta i nivå med den pubo-cervikalringen och ser till att nätmplantatet sträcks med vagina när VSD placeras korrekt.

Vid bakre reparation, fäst nätmplantatet i bakre cervix i nivå med den pubo-cervikalringen eller ovanför. Cut-de-sac kan öppnas när nätmplantatet fästs vid cervix. Stäng cut-de-sacsens peritoneum ovanför denna sutur för att förhindra att tarmer fäster vid nätmplantatet. Om kirurgen väljer att inte öppna cut-de-sac, exponeras den pubo-cervikalringen under bakre vaginaldissektion. En 2-0 PROLENE-sutur placeras stadigt i pubo-cervikalringens bakre yta. Suturen placeras också genom nätmplantatets apikala flik. PROLENE-suturen knys efter att nätmplantatets remmar är på plats. Detta säkrar nätmplantatet till den bakre ytan av cervix i nivå med den pubo-cervikalringen.

När nätmplantatet används till både främre och bakre vaginalreparation ska de fixeras till främre och bakre ytor av cervix som beskrivs ovan (se figur 11).

Nätimplantatshygien

Under operationer, spola vaginalsåren med koksaltlösning. Håll hanteringen av nätmplantatet till ett minimum och iaktta god implantatshygien.

Placering av VSD och ballong

Efter att operationen har slutförts, placera en VSD med fastsatt ballong av lämplig storlek i vagina och fäst den med sutur på plats för att förhindra förflyttning. VSD:n har tre möjliga storlekar (liten, mellan och stor) och kan anpassas av kirurgen för att passa patientens vaginallängd enligt följande.

VSD passing och tillklippning

VSD levereras i dess största storlek. Fastställ vilken VSD-storlek som är lämplig för patienten genom att använda VSD för att bedöma dess passing till patienten. Detta görs genom att placera VSD i största storleken i vagina mellan den sträckta apex och hymenringen. För att föra in VSD i vagina, ta tag i den bredaste punkten på VSD och vik längs längdaxeln med ballongen vänd uppåt (se figur 12). Den bredaste punkten på VSD förs in först så att suturhålen placeras precis ovanför hymenringen. **ANM: Lossa eller skada inte ballongen under VSD-anpassning.** Korrekt storlek uppnås när VSD passar tätt i den övre 2/3 av den sträckta vaginan med den distala änden och suturöglorna 1 cm ovanför hymenringen (se figur 13).

Om den stora storleken passar modifieras inte VSD. Om mellanstorleken behövs, avlägsnas det översta avsnittet genom att försiktigt, endast med spetsarna på en bjud Mayo-sax, klippa av små bitar och se till att få en jämnt klippt kant. Iaktta försiktighet för att minska mängden material som finns kvar i det klippda området. **ANM: Det är viktigt att passa in VSD naggant. När en VSD har klippts till kan den inte göras större och de klippda avsnitten kan inte fästas tillbaka.** Flytta undan ballongen under tillklippning (se figur 14). **Iaktta försiktighet för att undvika att skada ballongen under tillklippning av VSD.**

Om mellanstorleken passar behövs ingen vidare tillklippning. Om den minsta storleken krävs avlägsnas det kvarvarande avsnittet enligt beskrivningen ovan. Flytta undan ballongen under tillklippning så att den inte skadas.

När VSD-storleken har anpassats och ballongen satts på plats igen, kan enheten föras in i patientens vagina. **ANM: För att minska risken för perforering av ballongen, använd inga instrument för att hjälpa till vid införingen av VSD och ballongen.** Om ballongen skadas, avlägsna den från VSD och använd gasvävsförband för att fylla vaginalhålan.

Efter att enheten positionerats ordentligt i den övre 2/3 av patientens sträckta vagina, säkra VSD på plats genom att placera en enkel suturögla genom varje suturhål på VSD och i den bakre vaginalväggens epitel, lateralt och ovanför hymen på varje sida, som visas i figur 15, placerade klockan fyra och åtta. Höger och vänster suturer knys sen i tur och ordning och håller VSD på plats inuti vagina. **ANM: Iaktta försiktighet så att inte ballongen punkteras när VSD sys på plats.** Suturen som 2-0 Coated VICRYL, eller liknande resorberbar sutur rekommenderas för denna användning.

Ballongfyllnad

Efter att VSD har fästs på plats med sutur, koppla fast den medföljande 50 ml-sprutan genom att vrida den för att låsa fast den på ballongens ventil. **ANM: Efter att VSD har placerats krävs en kateter för att undvika urinretention.** Efter fyllnad med en liten volym luft (se figur 16), palpiera hela ballonglängden med ett finger för att se till att ballongen har vecklat ut sig och sitter längs hela vagina. När utveckling har bekräftats, avlägsna fingret och fortsätt att fylla ballongen helt tills endast en fingerspets passar tätt i ingången mellan ballongen och vaginalväggen. Stabilisering av VSD rekommenderas under fyllnad. Den fyllda ballongen används för att pressa nätmplantatet mot vaginalväggen. Luftvolymen som krävs för att få adekvat fyllnad av ballongen varierar från patient till patient. **ANM: Maximal ballongfyllnad får inte överstiga 90 ml.** När ballongen fyllts tillräckligt, koppla loss sprutan från ventilen genom att vrida den. Ballongens fyllnadslängd måste sträcka sig ut från vagina och fästas till patientens lår. Locket måste fästas på ballongens ventil för att se till att ballongen behåller den fastställda luftvolymen (se figur 7). **ANM: Dra inte åt locket för hårt.** Vid behov kan ballongen justeras senare, med en standardspruta för att öka eller minska luftvolymen i ballongen. Ballongen kan palperas när som helst eller inspekteras visuellt för att se till att den behåller tillräcklig fyllnad. **ANM: När patienten rör sig, lägger sig ballongen till rätta i vaginalhålan och kan verka öka eller minska i tryck. Detta är normalt.**

ANM: Koppla inte loss ballongen från VSD före användning.

ANM: Fyll inte ballongen innan den förs in i vagina.

ANM: Om VSD:s suturhål har förflyttat sig mer än 1 cm ovanför hymenringen eller om det är för hög spänning på suturerna efter ballongfyllnad, minska trycket i ballongen och omplacera eller anpassa storleken på VSD.

ANM: Om hål eller läckor uppträcks i ballongen eller om ballongen inte håller sin fyllnad, ANVÄND INTE ballongen. Den ska avlägsnas från VSD:n och kasseras på lämpligt sätt. Använd gasvävsförband istället för ballongen.

ANM: Om ballongens kopplingsdon lossnar från VSD, ska den tryckas tillbaka på plats.

ANM: Säkra inte ballongens fyllnadslang i vagina.

ANM: För att förhindra skada, utsätt inte fyllnadsslangen för extrem böjning, sträckning eller vridning.

ANM: Använd inte gasvävsförband samtidigt som ballong.

Avlägsnande av ballongen från VSD

Om ballongen helt med en standardspruta och ta bort den en dag efter operationen, men lämna kvar VSD. **ANM: Lämna inte ballongen i vagina mer än en dag.**

1) Ta bort locket från ballongens ventil.

2) Koppla en 50 ml (eller större) spruta till ballongens ventil och töm ballongen helt (se figur 17). Det är viktigt att tömma ballongen helt innan den avlägsnas från VSD. **ANM: En helt tömd ballong får sprutans kolv att dra sig tillbaka efter att ha tömt ut all luft.**

3) Ta bort sprutan.

4) Ballongen kan avskiljas från VSD och avlägsnas från patienten genom ett försiktigt ryck i kaudal riktning på fyllnadsslangen nära ballongens kopplingsdon, medan försiktigt mottryck ges på VSD:s distala ände med ett finger. Se figur 18.

ANM: Dra inte tillbaka ballongen förrän den är helt tömd och inget motstånd känns. Om du känner motstånd, fastställ orsaken innan du fortsätter. Om du fortsätter att föra inte eller dra tillbaka ballongen när du känner motstånd, kan det leda till att VSD förflyttar sig och/eller att vävnaden i vaginalhålan skadas. Se till att ballongen har tömts helt genom att ansluta sprutan igen och avlägsna all luft innan du fortsätter att ta bort ballongen.

Avlägsnande av VSD från patienten

Avlägsna VSD från patienten ungefär 3 till 4 veckor efter operationen efter att tillräcklig läkning har uppnåtts. Vid detta laget kan de resorberbara suturerna ha lösts upp eller förlorat tillräckligt med draghållfasthet för att tillåta att VSD avlägsnas utan suturmotsstånd. **ANM: Båda suturerna kan behöva klippas för avlägsnande. ANM: Lämna inte kvar VSD i patienten mer än 4 veckor.** Ta bort kvarvarande VSD-suturer. Avlägsna VSD manuellt från vaginalkanalen, som visas i figur 19.

Perioperativ vård

Patienter kan få profylaktisk antibiotika doserad enligt kirurgens vanliga rutiner. Antibiotikabehandling kan fortsättas postoperativt beroende på kirurgens preferenser. Tromboembolisk profylax kan användas.

Kirurgen ska förklara att syftet med VSD, som förblir i vagina i upp till fyra veckor efter operationen, är att stödja nätmplantatet mot vaginalväggen under läkningsperioden. Patienten ska informeras om att VSD kommer att avlägsnas vid en kontroll efter operationen – ungefär 4 veckor efter. Patienten ska informeras om att vaginalblåsing kan förekomma efter operationen och att VSD kan förflyttas lite nedåt. Om patienten känner att VSD har förflyttats nedåt, kan hon försiktigt skjuta den upp till ett mer bekvämt läge. Om VSD orsakar signifikanta besvär ska patienten kontakta sin läkare.

Efter utskrivning från sjukhuset, ska patienten instrueras att undvika ansträngande aktivitet under 3 till 4 veckor. Vid det laget har bäckenvävnad vävt in i nätmplantatet och patienten kan återuppta aktiviteter i det normala dagliga livet. Patienten ska avrådas från att ha samlag i 6 veckor efter operationen. Bäckentvoträning kan rekommenderas när som helst efter operation.

PRESTANDA

Djurstudier visar att implantation av GYNECARE GYNEMESH PS framkallar en minimal till lindrig inflammatorisk reaktion, vilken är övergående och efterföljs av deponering av ett tunt bindvävslager som kan växa igenom nätmaskorna så att nätet införilras med inliggande vävnad. Nätet förblir mjukt och formbart och den normala särkärningen påverkas inte märkbart. Materialet resorberas inte och bryts inte heller ned eller försvagas av vävnadsenzymmer.

KONTRAINDIKATIONER

- Vid användning av GYNECARE GYNEMESH PS på spädbarn, barn, gravida eller kvinnor som planerar framtida graviditet skall kirurgen vara medveten om att denna produkt inte kan sträckas i någon signifikant omfattning efterhand som patienten växer.
- GYNECARE PROSIMA-systemet ska inte användas vid graviditet eller variga infektioner eller cancer i vagina, cervix eller uterus.

VARNINGAR OCH FÖRSIKTIGHETSÅTGÄRDER

- Användare ska ha erfarenhet av operationsteknik som används vid reparation av bäckenbotten samt icke resorberbara nät innan de börjar använda GYNECARE PROSIMA-systemen.
- Användning av GYNECARE PROSIMA-systemet har inte utvärderats hos patienter med prolaps av bäckenorgan i stadium IV. Användning hos den här typen av patienter rekommenderas inte.
- Korrekt kirurgiska rutiner skall följas under ingreppet med GYNECARE PROSIMA liksom för hanteringen av kontaminerade eller infekterade sår.
- Om misstanke föreligger om att operationsområdet är infekterat eller kontaminerat för GYNECARE PROSIMA-systemet inte användas. Om nätmplantatet eller VSD-ballong-enheten används i kontaminerade områden, måste detta ske med insikten om att efterföljande infektioner kan nödvändiggöra att de avlägsnas.
- Efter operationen bör patienten rådas att avstå från tunga lyft och/eller motion (t.ex. cykling, jogging) i tre till fyra veckor och att avstå från samlag i sex veckor tills läkaren meddelar att det är lämpligt för patienten att återgå till sina normala aktiviteter.
- Lämna inte VSD i vagina i mer än fyra veckor.
- Lämna inte ballongen i vagina mer än 1 dag.
- Komponenterna till GYNECARE PROSIMA-systemet är inte avsedda att användas med någon annan enhet är de som anges i denna förpackningsinlägga.
- Undvik att belasta nätmplantatet kraftigt vid behandlingen.
- Använd GYNECARE PROSIMA-systemen med försiktighet och var uppmärksam på patientens anatomi för att undvika skada på kärl, nerver, blåsa, tarmar och perforering av vaginalväggen. Om komponenterna till GYNECARE PROSIMA-systemet används korrekt minimeras riskerna.
- Fyll endast ballongen med omgivningsluft.
- Palpation bekräftar att ballongen inte innehåller luftläckor efter fyllnad. Total förlust av fyllnad kan bekräftas ballongens effektivitet.
- Ballongens väggar är tunna för att kunna uppnå önskade egenskaper. Punktering, snitt, hack eller överansträngning kan leda till fyllnadsförlust. Ballongen kan lätt penetreras av en nål eller skalpell eller gå sönder om det hanteras med ett trubbig föremål. Försiktighet måste iaktas under hantering för att undvika sådana händelser. En skadad ballong får inte användas. Avlägsna och packa med gasvävsförband.
- Ballongen får fyllas med maximalt 90 ml. Överfyll inte ballongen. Vid för hög fyllnad kan patienten känna obehag. Det kan också orsaka vävnadsnekros, skada på vaginalsåret efter operation och oförmåga till tömning.
- Utför inte ingrepp med GYNECARE PROSIMA-systemen på patienter som behandlas med antikogulantia.
- Postoperativ blödning kan förekomma. Undersök om symptom eller tecken på blödning föreligger innan patienten skrivs ut från sjukhuset.
- Patienten ska instrueras att omgående kontakta läkaren om ovanlig smärta, blödning eller andra problem uppstår.
- Trots att skada på blåsa troligtvis inte uppstår med denna teknik, rekommenderas att en cytoskopi utförs.
- Trots att skada på rektum troligtvis inte uppstår med denna teknik, krävs att en digital undersökning utförs.
- GYNECARE GYNEMESH PS-nätet får inte komma i kontakt med suturklamrar, clips eller klämmare, eftersom mekaniska skador på nätet kan uppstå.

- Nätmplantatet ska inte täcka någon del av den nedre tredjedelen av vagina. Klipp till nätmplantatet vid behov så att det passar övergången mellan nedre och mittersta tredjedelen av vaginalväggen.
- Profylaktisk antibiotikabehandling kan tillämpas enligt kirurgens sedvanliga praxis.

BIVERKNINGAR

- Möjliga biverkningar är sådana som vanligen kan sättas i samband med kirurgiska implantat, däribland infektion, inflammation, adhärens bildning, fistelbildning, erosion, avstötning och ärrbildning som kan leda till kontraktion av implantatet.
- Möjliga biverkningar är sådana som vanligen kan sättas i samband med ingrepp för reparation av prolaps av bäckenorgan, däribland smärta vid samlag och bäckensmärta. Dessa kan lösas sig själva med tiden.
- Punktion eller laceration eller skada på blodkärl, nerver, urinblåsa, uretra eller tarm kan förekomma i samband med dissektion eller nätplacering och kan kräva kirurgisk reparation.
- Dissektion vid reparation av bäckenbotten kan möjligtvis påverka normal tännning för en öka lång tid.

STERILITET

GYNECARE PROSIMA-systemen är steriliserade med etylenoxid. STERILISERA INTE OM någon del av GYNECARE PROSIMA-systemet. ÅTERANVÄND INTE någon del av GYNECARE PROSIMA-systemet. Återanvändning av anordningen (eller delar av den) kan orsaka en degradering av produkten och kontamination vilket kan leda till infektioner eller överföring av blodburna patogener till patienter och användare. Produkterna får ej användas om förpackningen varit öppnad tidigare eller är skadad. Kassera oanvända komponenter till GYNECARE PROSIMA-systemet vars förpackningar har öppnats.

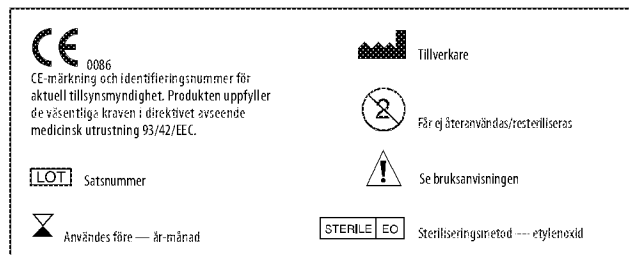
KASSERING

Kassera komponenter till GYNECARE PROSIMA-systemet enligt de regler och rutiner som gäller på din arbetsplats för hantering av biologiskt riskavfall.

FÖRVARING

Rekommenderade förvaringsförhållanden: kontrollerad rumstemperatur och relativ luftfuktighet (cirka 25 °C, 60 % relativ luftfuktighet). Skyddas mot luft och direkt värme. Får ej användas efter utgångsdatum.

Symboler på etiketterna



Gynecare PROSIMA™

Σύστημα αποκατάστασης πρόσθιου πυελικού εδάφους
Σύστημα αποκατάστασης οπίσθιου πυελικού εδάφους
Συνδυασμένο σύστημα αποκατάστασης πυελικού εδάφους

Διαβάστε προσεκτικά όλες τις πληροφορίες.

Εάν δεν ακολουθήσετε σωστά τις οδηγίες, οι συσκευές ενδέχεται να μη λειτουργήσουν σωστά και να προκαλέσει τραυματισμό.

PROFAX. Η ομοιοπαθητική νοσηλεύσα (των Η.Π.Α.) περιορίζει την πώληση της συσκευής αυτής σε ιατρούς ή κάποιον εντολίστη (ιατρός).

Συνιστάται, και είναι διαθέσιμη, εκπαίδευση στη χρήση των συστημάτων αποκατάστασης πυελικού εδάφους GYNECARE PROSIMA™. Επικοινωνήστε με τον αντιπρόσωπο πωλήσεων της εταιρείας για να προγραμματίσετε την εκπαίδευση αυτή.

ΕΝΔΕΙΞΗ

Τα συστήματα αποκατάστασης πυελικού εδάφους GYNECARE PROSIMA, μέσω της τοποθέτησής με απορροφητήριων εμφυτευμάτων μαλακού πλέγματος GYNECARE GYNEMESH™ PS από PROLENE™, προορίζονται για ενίσχυση ιστού και για μακροχρόνια σταθεροποίηση των περιτοναϊκών δομών του πυελικού εδάφους, είτε ως μηχανικό υποστήριγμα είτε ως υλικό γεφύρωσης της ελλείμματος της σκηνώσεως. Τα συστήματα παρέχουν διατήρηση του κοιλιακού σπλάγνα κατά τη διάρκεια της φυσιολογικής κίνησης, έλκεται από χειρουργική αποκατάσταση της πρόπτωσης του κοιλιακού τοιχώματος, ενώ ταυτόχρονα υποστηρίζουν την τοποθέτηση των εμφυτευμάτων πλέγματος.

ΠΕΡΙΓΡΑΦΗ

Τα συστήματα αποκατάστασης πρόσθιου και οπίσθιου πυελικού εδάφους, καθώς και το συνδυασμένο σύστημα αποκατάστασης πυελικού εδάφους GYNECARE PROSIMA, αποτελούνται από ήδη κομμένο εμφύτευμα πλέγματος GYNECARE GYNEMESH PS και από εργαλείο για τη διευκόλυνση της τοποθέτησής και της μεταχειρουργικής στήριξης των εμφυτευμάτων πλέγματος (βλ. εικόνα 1). Ο παρακάτω πίνακας παρουσιάζει συνοπτικά τα εξαρτήματα που περιλαμβάνονται σε κάθε σύστημα.

ΣΥΣΤΗΜΑ ΑΠΟΚΑΤΑ- ΣΤΑΣΗΣ ΠΥΕΛΙΚΗ ΕΔΑΦΟΥΣ	ΕΞΑΡΤΗΜΑΤΑ (βλ. εικόνα 1)				
	Εμφύτευμα πλέγματος σε φορέα (Α)	Διάταξη κοιλιακής υποστήριξης – διάταξη μυελονοού (Β και Γ)	Πρόσθιος εισαγωγέας (D)	Οπίσθιος εισαγωγέας (Ε)	Σόρην (F)
Πρόσθιο	1	1	1		1
Οπίσθιο	1	1		1	1
Συνδυασμένο	2	1	1	1	1

Πίνακας 1 – Εξαρτήματα συστήματος αποκατάστασης πυελικού εδάφους GYNECARE PROSIMA

GYNECARE GYNEMESH PS

Το πλέγμα GYNECARE GYNEMESH PS κατασκευάζεται από πλεκτό νήματα εξωθημένου πολυπροπυλενίου, πανομοιότυπο σε σύνθεση με το πλέγμα πολυπροπυλενίου από PROLENE™ (ETHCON, INC.). Το υλικό αυτό, όταν χρησιμοποιείται ως πλέγμα, έχει αναφερθεί ότι είναι μη δραστικό και ότι διατηρεί την αντοχή του επί ορόσημο κατά την κλινική χρήση. Το πλέγμα χαρακτηρίζεται από εξαιρετική αντοχή, διάρκεια ζωής και δυνατότητα προσαρμογής σε διάφορες χειρουργικές τεχνικές, καθώς διαθέτει επεκτάσιμη πορώδη δομή που επιτρέπει την απαραίτητη διείσδυση ιστών. Για τη δημιουργία μακρών αντίθεσης στο πλέγμα, έχουν ενσωματωθεί μεμονωμένα μπάλες νήματος PROLENE. Το πλέγμα κατασκευάζεται από μονόκλωνες ίνες μειωμένης διαμέτρου, πλεγμένες σύμφωνα με ένα μοναδικό σχέδιο που σχηματίζει πλέγμα, το οποίο είναι περίπου 50 τοις εκατό πιο ελαφρύ από το τυπικό πλέγμα πολυπροπυλενίου PROLENE™. Το πλέγμα πλέκεται με μια διαδικασία που συνδέει μεταξύ τους τις ενόσεις των νηών, εξασφαλίζοντας έτσι ελαστικότητα και προς τις δύο κατευθύνσεις. Η κατασκευή αυτή επιτρέπει την κοπή του πλέγματος σε οποιαδήποτε επιθυμητή σχήμα ή μέγεθος, χωρίς να ζητυλώνεται. Η ελαστικότητα προς δύο κατευθύνσεις επιτρέπει την προσαρμογή του στις διάφορες τάσεις που αναπτύσσονται στο σώμα.

Εμφύτευμα πλέγματος

Το εμφύτευμα πλέγματος κατασκευάζεται από GYNECARE GYNEMESH PS. Το εμφύτευμα πλέγματος είναι ήδη κομμένο σε σχήμα Υ για την αποκατάσταση πρόσθιου, οπίσθιου και/ή κορυφαίου κοιλιακού ελλείμματος. Βλ. εικόνα 2. Το εμφύτευμα πλέγματος διαθέτει 2 μόντες και ένα κεντρικό σώμα. Στο περιφερικό άκρο υπάρχει μια κορυφαία γλωττίδα, για τη συρραφή με ράβιμα, ώστε να ελαχιστοποιείται η μετατόπιση του εμφυτεύματος πλέγματος κατά τη διάρκεια της τοποθέτησής του. Στο περιφερικό άκρο υπάρχει μια περιφερική αλυσάκι η οποία βοηθά στην ευθυγράμμιση του εμφυτεύματος πλέγματος. Στους μόντες του εμφυτεύματος πλέγματος υπάρχουν ήδη σχηματισμένοι θύλακες, τα οποία επιτρέπουν την τοποθέτησή του με τους εισαγωγείς. Το εμφύτευμα πλέγματος διατίθεται μέσα σε ένα φορέα εμφυτεύματος, ο οποίος αποτελείται από μη ελαστικό Tyvek® και από μια καθαρή πλαστική μεμβράνη, σχεδιασμένη για την εύκολη αφαίρεση του εμφυτεύματος πλέγματος.

Πρόσθιος εισαγωγέας

Ο πρόσθιος εισαγωγέας είναι ένα εργαλείο σχεδιασμένο για να διευκολύνει την εισαγωγή των μόντων του εμφυτεύματος πλέγματος μέσα στους πρόσθιους θύλους του ανετημένου ιστού, το οποίο προορίζεται για χρήση σε μία μόνον ασθενή.

ΣΗΜΕΙΩΣΗ: Ο πρόσθιος εισαγωγέας δ **ια διαχωρισμό ιστών.** Ο πρόσθιος εισαγωγέας είναι σχεδιασμένος ώστε να είναι συμβατός με τα θύλακα του εμφυτεύματος πλέγματος, για να επιτρέπει την τοποθέτησή των μόντων και στις δύο πλευρές της σκηνώσεως, στο πρόσθιο διαμέρισμα. Βλ. εικόνα 3 και 4.

Οπίσθιος εισαγωγέας

Ο οπίσθιος εισαγωγέας είναι ένα εργαλείο σχεδιασμένο για να διευκολύνει την εισαγωγή των μόντων του εμφυτεύματος πλέγματος μέσα στους οπίσθιους θύλους του ανετημένου ιστού, το οποίο προορίζεται για χρήση σε μία μόνον ασθενή.

ΣΗΜΕΙΩΣΗ: Ο οπίσθιος εισαγωγέας δεν προορίζεται για το διαχωρισμό ιστών. Ένα τυπικό θελικό κατά τη/οιδήποτε είναι προσαρμοσμένο στον οπίσθιο εισαγωγέα ως σταθεροποιητής, για ελεγχόμενη εισαγωγή. Ο οπίσθιος εισαγωγέας είναι σχεδιασμένος ώστε να είναι συμβατός με τα θύλακα του εμφυτεύματος πλέγματος, για να επιτρέπει την τοποθέτησή των μόντων και στις δύο πλευρές της σκηνώσεως, στο οπίσθιο διαμέρισμα. Βλ. εικόνα 5.

Διόταξη Κοιλιακής Υποστήριξης (ΔΚΥ)

Η ΔΚΥ είναι μια συσκευή για χρήση σε μία μόνον ασθενή, σχεδιασμένη να παρέχει μεταχειρουργική υποστήριξη στους κοιλιακούς ιστούς μετά την τοποθέτηση του πλέγματος και τη σύγκλειση της κοιλιακής τομής ή τομών. Το κορυφαίο άκρο είναι το πλαστικό άκρο της ΔΚΥ και περιλαμβάνει αποκολλημένα τμήματα. Μετά την αρχική ρύθμιση του μεγέθους μέσα στο σώμα της ασθενούς, το μέγεθος της ΔΚΥ μπορεί να ρυθμιστεί, ώστε να προσαρμοστεί στην ανατομία της ασθενούς, με την αποκοπή των καθορισμένων κορυφαίων τμημάτων. Η ΔΚΥ παραμένει στο άνω 2/3 του κόλπου επί 3 έως 4 εβδομάδες και στη συνέχεια αφαιρείται από την ασθενή. Βλ. εικόνα 6.

Μπαλόνι

Το μπαλόνι είναι μια συσκευή σχεδιασμένη να αντικαθιστά τη μεταχειρουργική τοποθέτηση γαζών στον κόλπο, η οποία προορίζεται για χρήση σε μία μόνον ασθενή. Ο όγκος του μπαλονιού μπορεί να ρυθμιστεί, έτσι ώστε να γεμίσει τον κοιλιακό σπλάγνα και να εφαρμόζει το εμφύτευμα πλέγματος στο κοιλιακό τοίχωμα. Το μπαλόνι διατίθεται ήδη προσαρμοσμένο στη ΔΚΥ. Η εικόνα 7 απεικονίζει το αποδοκιμαζόμενο μπαλόνι χωρίς τη ΔΚΥ προσαρμοσμένη σε αυτό. Το μπαλόνι παραμένει στην ασθενή επί 3 έως 4 εβδομάδες.

Σόρην

Διατίθεται μια σόρην των 50 cm για τη διόγκωση του μπαλονιού.

ΕΝΟΤΗΤΑ 1: ΑΡΧΕΣ ΤΗΣ ΔΙΑΔΙΚΑΣΙΑΣ ΜΕ ΧΡΗΣΗ ΤΟΥ ΣΥΣΤΗΜΑΤΟΣ GYNECARE PROSIMA

Η διαδικασία αποκατάστασης του πυελικού εδάφους με χρήση του συστήματος GYNECARE PROSIMA στοχεύει στην ανατομική, ανθεκτική και ταυτοποιημένη αποκατάσταση της πρόπτωσης των οργάνων της πυέλου. Ανάλογα με το σημείο της πρόπτωσης και την προτίμηση του χειρουργού, η αποκατάσταση μπορεί να είναι πρόσθια και/ή οπίσθια. Η υστερεκτομή ή η διατήρηση μήτρας μπορούν να συνδυαστούν με τη διαδικασία με χρήση του συστήματος GYNECARE PROSIMA. Εάν ενδεικνύεται, μπορούν να εκτελεστούν ταυτόχρονα περικνηκή αποκατάσταση ή επέμβαση τοποθέτησης υπο-ομφυλικής σφενδόνης για τη θεραπεία της ακράτειας ούρων από προσέγγιση, όταν χρησιμοποιείται το σύστημα GYNECARE PROSIMA. Μπορεί να χρησιμοποιηθεί μια υποστηρίξη ή μια διαθυροειδής υπο-ομφυλική σφενδόνη.

Η αποκατάσταση της πρόπτωσης επιτυγχάνεται με την τοποθέτηση 1 ή 2 εμφυτευμάτων πλέγματος μέσω κοιλιακής προσέγγισης. Μετά την ολοκλήρωση της χειρουργικής επέμβασης, τοποθετείται στον κόλπο μια ΔΚΥ με διατελλόμενο μπαλόνι, προκειμένου να ρυθμιστεί το μέγεθος και, στη συνέχεια, η ΔΚΥ αφαιρείται. Στη θέση της, παρέχοντας έτσι υποστήριξη στον κόλπο και στο εμφύτευμα ή στα εμφυτεύματα πλέγματος, κατά τη διάρκεια της διείσδυσης ιστών. Αφού διασταλεί, το μπαλόνι αντικαθιστά τη στήριξη τοποθέτηση γαζών στον κόλπο, γεμίζοντας την κοιλιακή κοιλότητα και στηρίζοντας το εμφύτευμα ή τα εμφυτεύματα πλέγματος στον κόλπο. Την επόμενη ημέρα από τη χειρουργική επέμβαση, το μπαλόνι αποδοκιμάζεται και αφαιρείται από τον κόλπο χωρίς να ανακαταλάβει η ΔΚΥ. Η ΔΚΥ παραμένει στη θέση της επί 3 έως 4 εβδομάδες μετά τη χειρουργική επέμβαση, κατά τη διάρκεια της διείσδυσης ιστών μέσα στο εμφύτευμα ή στα εμφυτεύματα πλέγματος.

ΕΝΟΤΗΤΑ 2: ΣΚΗΜΑΤΑ ΤΟΥ ΣΥΣΤΗΜΑΤΟΣ GYNECARE PROSIMA

Έπειτα από μια ομαλή και/ή επιβίβαση λόγω πρόπτωσης πυελικού οργάνου, οι αποκαταστημένοι ιστοί εκτείνονται σε αυξημένης ενδοκοιλιακής πίεσης, καθώς η ασθενής κινητοποιείται, βήχει, εξέρει και καταπονείται κατά την εκκένωση των εντέρων. Αυτές οι αυξήσεις στην ενδοκοιλιακή πίεση ενδέχεται να επηρεάσουν δυσμενώς την επώδυνη της κακής αποκατάστασης και να οδηγήσουν σε αποτυχία της επέμβασης και σε υποτροπιάζουσα πρόπτωση. Ενισχύοντας την κοιλιακή αποκατάσταση με το εμφύτευμα πλέγματος και υποστηρίζοντας τον κόλπο με τη ΔΚΥ επί 3 έως 4 εβδομάδες μετά τη χειρουργική επέμβαση, το σύστημα GYNECARE PROSIMA είναι σχεδιασμένο έτσι ώστε να μειώνει τον κίνδυνο αποτυχίας της επέμβασης και υποτροπής της πρόπτωσης.

Κατά την πρόσθια κοιλιακή αποκατάσταση, το σώμα του εμφυτεύματος πλέγματος προορίζεται να τοποθετηθεί χωρίς τάση ανάμεσα στην ουροδόχο κύστη και στο άνω 2/3 του κόλπου, εκτεινόμενο πλευρικά στο επίπεδο του τευνοειδούς τόξου της πυελικής περιτονώσεως (ΠΠΠ). Κατά την οπίσθια κοιλιακή αποκατάσταση, το σώμα του εμφυτεύματος πλέγματος προορίζεται να τοποθετηθεί χωρίς τάση ανάμεσα στο ορθό και στο άνω 2/3 του κόλπου, εφαρμόζοντας πλευρικά επάνω από τον ανελκυστήρα μη νού ηρωτικό. Το κορυφαίο τμήμα του σώματος του εμφυτεύματος πλέγματος προορίζεται να φθάσει έως την κορυφή του κόλπου. Πρόσθια, το εμφύτευμα πλέγματος μπορεί να συρραφεί στον προ-ορθικό ιστό ή στον τραχήλο. Οπίσθια, το εμφύτευμα πλέγματος μπορεί να συρραφεί στον προ-ορθικό ιστό ή στον τραχήλο.

Η ΔΚΥ υποστηρίζει του κοιλιακού ιστούς μετά τη χειρουργική επέμβαση και διευκολύνει την εφαρμογή των κοιλιακών ιστών στο εμφύτευμα πλέγματος έως ότου πραγματοποιηθεί η διείσδυση ιστών. Η διείσδυση ιστών διαμέσου του εμφυτεύματος πλέγματος πραγματοποιείται κατά τη διάρκεια των 3 έως 4 εβδομάδων μετά την επέμβαση. Με χρήση του συστήματος GYNECARE PROSIMA υποβοηθείται η ανάκληση διαχωρισμού ιστών εκτός της πυελικής κοιλότητας, καθώς επίσης και τη διείσδυση ραβμάτων και εργαλείων διαμέσου του θωρακικού τμήματος και του τευνοειδούς συνδέσμου, επιδυνάμυνοντας έτσι την εκτέλεση της μεταχειρουργικής επέμβασης.

Υστερεκτομή

Η πρόπτωση του χειρουργού και οι συνέπειες της ασθενούς καθορίζουν εάν απαιτείται συνδυαστική υστερεκτομή. Όταν πραγματοποιείται υστερεκτομή, συνιστάται σύγκλειση της τομής κοιλότητας του περιτόνιου, ώστε να αποτραπεί τυχόν επαφή του εμφυτεύματος πλέγματος με το έντερο. Θα πρέπει να αποφευχθεί σύγκλειση με τομή σχήματος «I», καθώς αυτό ενδέχεται να αυξήσει τον κίνδυνο έκθεσης του πλέγματος. Όταν εκτελείται κοιλιακή υστερεκτομή μαζί με πρόσθια ή οπίσθια αποκατάσταση ή με συνδυασμό και των δύο, θα πρέπει πρώτα να ολοκληρωθεί η εγκάρσια σύγκλειση της τομής της υστερεκτομής, και στη συνέχεια, οι τομές αποκατάστασης θα πρέπει να γίνουν με τέτοιο τρόπο ώστε να μη συνδέονται με την τομή υστερεκτομής την οποία προηγήθηκε η σύγκλειση. Αυτό γίνεται για να αποτραπεί η δημιουργία τομής σχήματος «I».

Διατήρηση μήτρας

Το σύστημα GYNECARE PROSIMA είναι κατάλληλο για περιπτώσεις όπου ο χειρουργός ή η ασθενής επιλέγουν τη διατήρηση της μήτρας.

ΕΛΛΗΝΙΚΑ

Κολπικές τομές

Οι κολπικές τομές στη διαδικασία με χρήση του συστήματος GYNECARE PROSIMA είναι ίδιες με εκείνες που χρησιμοποιούνται από το χειρουργό στις συνήθεις επεμβάσεις κολπικής αποκατάστασης. Οι τομές θα πρέπει να γίνονται σε όλο το βάθος του κολπικού τοιχώματος, ώστε να μειωθεί η πιθανότητα έκθεσης του πλέγματος.

Τοποθέτηση του εμφυτεύματος πλέγματος

Το εμφύτευμα πλέγματος συγκρατούνται στη θέση τους από τη ΔΚΥ μέχρις ότου πραγματοποιηθεί η διεύθυνση ιστών. Επακόλουθ, δεν είναι απαραίτητο να στερεωθούν οι μόνες του εμφυτεύματος πλέγματος στη θέση τους. Το κορυφαίο τμήμα του εμφυτεύματος πλέγματος μπορεί να ασφαριστεί στην περιτονία στη μέση γραμμή, στην κορυφή του κόλπου, χρησιμοποιώντας ένα ράμμα όπως το MONOCRYL™ (πολυλυσκροπρόνη 25) 2-0 ή το επικαλυμμένο ράμμα Coated VICRYL™ (πολυλυσκροπρόνη 910) 2-0. Το κολπικό επιθήλιο δεν πρέπει να ασφαριστεί επάνω στο εμφύτευμα πλέγματος.

Προφύλαξη του κόλπου

Θα πρέπει να αποφεύγεται η υπερβολική σφύριση ή εκτομή κολπικού επιθηλίου. Μετά την επέμβαση ενδέχεται να παρουσιαστεί μερική διαστολή του ιστού, και η μειωμένη κολπική χωρητικότητα μπορεί να επιδεινωθεί εάν έχει ασφαριθεί μεγάλη ποσότητα κολπικού επιθηλίου.

Τρία επίπεδα υποστήριξης του κόλπου

Υπάρχουν 3 επίπεδα υποστήριξης του κόλπου, κοινώς γνωστά ως κολπική αποκατάσταση. Η χρήση του συστήματος GYNECARE PROSIMA σε μια διαδικασία προαρίζεται να παρέχει τα επίπεδα I και II αυτής της υποστήριξης, ως εξής:

Επίπεδο I - Ανάρτηση και υποστήριξη (άνω τριτημόριο του κόλπου)

Το άνω τριτημόριο του κόλπου (συμπεριλαμβανομένων του θύλου που δημιουργείται μετά από υστερεκτομή) και η μήτρα υποστηρίζονται από 2 μηχανισμούς. Κατά πρώτο λόγο, άμεση υποστήριξη στη μήτρα και στο άνω μέρος του κόλπου παρέχεται από τους του παρατηρούμενους κύριους συνδέσμους της μήτρας και τερονωτιακούς συνδέσμους) και τον συνδέσμο ιστού γύρω από τον κόλπο. Οι τρεις αυτές δυνάμεις συνδυάζονται ανάρτησης και εκκρίνονται από την περιτονία του επιπεδικού μύος, της μεσολιθικής αρθρώσεως και του πλευρικού τερόδ ιστού, ενώ εδωρύνονται στο πλευρικό άνω τριτημόριο του κόλπου και στην οπισθοσπληνική όψη του τριτημίου. Κατά δεύτερο λόγο, άμεση υποστήριξη στη μήτρα και στο άνω μέρος του κόλπου παρέχεται από την πλάκα του ανελκυστήρα που σχηματίζεται από την ένωση του δεξιού και του αριστερού ανελκυστήρα με τον πρακτικό, σιμωμένο στον πράκτο και τον κόκκο. Η πρόπτωση του θύλου της μήτρας και του κόλπου προκύπτει ως αποτέλεσμα της ανεπάρκειας αυτών των δυνάμεων και έμμεσων μηχανισμών υποστήριξης. Αυτό πιθανώς να οφείλεται σε αδυναμία των μυών του πλευρικού εδάφους και των μυών ανάρτησης του παραμυρίου και του συνδέσμου ιστού στην ανώτερη περιοχή γύρω από τον κόλπο. Σκοπός της χειρουργικής επέμβασης αποκατάστασης πρόπτωσης στο επίπεδο I, είναι να ενισχυθούν οι δυνάμεις και τους έμμεσους μηχανισμούς υποστήριξης. Το σύστημα GYNECARE PROSIMA χρησιμοποιεί τους μόνες του εμφυτεύματος πλέγματος για να εφαρμόσει επάνω σε κάθε έσω θύλο ένα ράμμα και στην υπερκείμενη τοιχωματική περιτονία, κατά την πρόδοση κολπική αποκατάσταση, ενώ οι μόνες του εμφυτεύματος πλέγματος υποστηρίζουν τους τερονωτιακούς συνδέσμους, κατά την οπίσθια κολπική αποκατάσταση. Με τον τρόπο αυτό, παρέχεται άμεση υποστήριξη μέσω ανάρτησης και έμμεση υποστήριξη μέσω της δημιουργίας μιας ευρείας περιοχής υποστήριξης από το εμφύτευμα πλέγματος για το άνω μέρος του κόλπου και τη μήτρα.

Επίπεδο II - Πλευρική πρόσφυση (μέσο τριτημόριο του κόλπου)

Το μέσο τμήμα του κόλπου προσφύεται πλευρικά και άμεσα στους μύες του πλευρικού πυελικού τοιχώματος, μέσω του τερονωτιακού ιστού της πυελικής περιτονίας (ΤΠΠ). Σε αυτό το επίπεδο, το πρόσθιο και το οπίσθιο τοίχωμα του κόλπου απεκκινούνται μεταξύ της δεξιάς και της αριστερής πλευρικής πρόσφυσης. Στο επίπεδο II, η επέμβαση αποκατάστασης πρόπτωσης στοχεύει στην εκ νέου πλευρική πρόσφυση του μέσου τμήματος του κόλπου στους μύες του πλευρικού πυελικού τοιχώματος. Το κεντρικό ελλείμμα στο μέσο τμήματος του κόλπου απαιτούν επίσης υποστήριξη στο επίπεδο II. Η χρήση του συστήματος GYNECARE PROSIMA σε μια διαδικασία ενισχύει την πλευρική πρόσφυση του κόλπου επάνω στους μύες του πλευρικού πυελικού τοιχώματος και παρέχει επίσης κεντρική ενίσχυση στην περιτονία μετά την ιστική διεύθυνση.

Επίπεδο III - Συγκώνωση (κάτω τριτημόριο του κόλπου)

ΣΗΜΕΙΩΣΗ: Κατά την χρήση του συστήματος GYNECARE PROSIMA δεν απαιτείται διαχωρισμός των ιστών σε αυτήν την περιοχή.

Στο επίπεδο III, πρόσθιο, το κάτω τριτημόριο του κόλπου συγκώνεται με τη περιωική μεμβράνη και την ουρήθρα. Οπίσθιο, το κάτω τριτημόριο του κόλπου συγκώνεται με το σπεντικό σώμα και με τους ανελκυστήρες μύες του πρακτικού. Η αποκατάσταση των ιστών σε αυτή την περιοχή γίνεται χωρίς το εμφύτευμα πλέγματος, καθώς το εμφύτευμα πλέγματος δεν προορίζεται για χρήση στο κάτω τριτημόριο του κόλπου. Το σύστημα GYNECARE PROSIMA δεν αντιμετωπίζει ελλείμματα υποστήριξης στο επίπεδο III, μελώντα αυτά μπορούν να αντιμετωπιστούν με συνδυασμένες επεμβάσεις, όπως η περινεοτομία.

ΕΚΘΕΤΗ 3: ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ

Σ

ισή προετοιμασία

Η χειρουργική επέμβαση που πραγματοποιείται με το σύστημα GYNECARE PROSIMA μπορεί να διεξαχθεί υπό γενική ή τοπική αναισθησία, ανάλογα με τις προτιμήσεις του χειρουργού, του αναισθησιολόγου και της ασθενούς.

Η ασθενής θα πρέπει να τοποθετηθεί στη θέση λήθου, με τους γλουτούς να προσέχουν ελαφρά από το χειρουργικό τραπέζι και με τα ισχία σε κάμψη. Κατά την κρίση του χειρουργού, μπορεί να γίνει παραγωγή της ουροδόχου κύστης, πριν από τη διεύθυνση του μυελονόου είναι απαραίτητη η τοποθέτηση ενός καθετήρα, ο οποίος μπορεί να εισαχθεί σε αυτό το χρονικό σημείο της επέμβασης.

Χρήση του συστήματος GYNECARE PROSIMA σε διαδικασίες μετά από υστερεκτομή

Πρόσθια κολπική αποκατάσταση

Όταν απαιτείται ενίσχυση μόνον του πρόσθιου κολπικού τοιχώματος, θα πρέπει να χρησιμοποιείται μόνο το σύστημα αποκατάστασης πρόσθιο πυελικού εδάφους GYNECARE PROSIMA. Αυτό περιλαμβάνει 1 εμφύτευμα πλέγματος και ένα ενικό σχεδιασμένο πρόσθιο εισαγωγέ για χρήση σε μια πρόσθια κολπική αποκατάσταση. Αφού γίνουν οι απαιτούμενες κολπικές τομές και ο διαχωρισμός των ιστών, δημιουργούνται διάλυμα στους ιστούς του πρόσθιου διαμερίσματος για την τοποθέτηση των μόνων του εμφυτεύματος πλέγματος με χρήση του πρόσθιου εισαγωγέα. **ΣΗΜΕΙΩΣΗ: Ο πρόσθιος εισαγωγέας δεν πρέπει να χρησιμοποιείται κατά τη διαχωρισμό ιστών.**

Πρόσθιος κολπικός διαχωρισμός

Το πρόσθιο κολπικό επιθήλιο διαχωρίζεται από την ουροδόχο κύστη, διαχωρίζεται το κολπικό τοίχωμα σε όλο το πάχος του. Ο διαχωρισμός αυτός θα πρέπει να διεκδικείται από υπερίσθιακ υδροδιαχωρισμό. Θα πρέπει να αποφευχθεί ο επιπεδικός διαχωρισμός του κολπικού τοιχώματος ή ο διαχωρισμός του κολπικού τοιχώματος σε 2 σπλάξεις. Ένας ελάχιστος διαχωρισμός ενδέχεται να καταβεί σε πολύ λεπτό κολπικό τοίχωμα και ενδέχεται επίσης να προκαλέσει προβλήματα στην ομίωση του κολπικού τοιχώματος, αυξανοντας έτσι τον κίνδυνο έκθεσης του εμφυτεύματος. Πλευρικά, συνεχίστε το διαχωρισμό προς το πλευρικό πυελικό τοίχωμα και έως την ισχιακή άκρη.

Πρόσθια διάνοξη διαύλων και τοποθέτηση του εμφυτεύματος πλέγματος

Για τους σκοπούς αυτής της περιγραφής, εκτελέστε το διαχωρισμό για τη δημιουργία των διαύλων για τους μόνες των εμφυτεύματος πλέγματος πρώτα στη δεξιά πλευρά της ασθενούς και έπειτα στην αριστερή. Οι διαύλοι αυτοί δημιουργούνται προκειμένου να τοποθετηθεί το εμφύτευμα πλέγματος έτσι ώστε το περιφερικό τμήμα των μόνων να βρίσκεται στον ίδιο επίπεδο με το πλευρικό πυελικό τοίχωμα και την τοιχωματική περιτονία του έσω θύλο-ουροδόχου μύος. Για την τοποθέτηση αυτών των μόνων, ξεκινήστε το διαχωρισμό των ιστών υπερκείμενης και αναγεννηζόντας την ισχιακή άκρη και στις δύο πλευρές. **ΣΗΜΕΙΩΣΗ: Ο διαχωρισμός αυτός μπορεί να εκτελεστεί με έναν 1 χρησιμοποιώντας την τεχνική "αδής διάνοξη" (split-spread), έτσι ώστε να άκρα του θύλου να παραμείνουν συνεχώς προσθίας της ισχιακής άκρης.** Συνήχστε τον αρχικό διαχωρισμό με ελαφρά δακτυλικό διαχωρισμό έως την ισχιακή άκρη. Μόλις αγγίξετε την ισχιακή άκρη, κινήστε κολπικά το δέκτη σας, ώστε να δημιουργηθεί ένας χώρος πρόσθια και επάνω από την ισχιακή άκρη. Βλ. εικόνα 8Α. Η κατεύθυνση αυτού του διαχωρισμού είναι: κατακόρυφη ως προς το πλευρικό πυελικό τοίχωμα και δημιουργεί ένα χώρο περίπου 2 cm σε πλάτος και 3 cm σε ύψος. Ο πρόσθιος διαχωρισμός ιστών δεν περιλαμβάνει διαχωρισμό στους τερονωτιακούς συνδέσμους. Αυτός ο διαχωρισμός δημιουργεί έναν διαύλο πρόσθια και επάνω από την ισχιακή άκρη και επάνω από το ΤΠΠ, τον έσω θύλο-ουροδόχο και την τοιχωματική περιτονία. Επανελαβετέ τον ίδιο διαχωρισμό στην αριστερή πλευρά.

Δεν απαιτείται πτύχωση του προ-κυστικού ιστού. Οπότε, εάν πραγματοποιηθεί πτύχωση, πτυχώνεται μόνο το κεντρικό τμήμα του ιστού αυτού. Με αυτό τον τρόπο, η περιοχή όπου γίνεται ο διαχωρισμός δεν γίνεται πολύ στενή. Τοποθετήστε το εμφύτευμα πλέγματος επάνω από τον προ-κυστικό ιστό, με τα θάλακα των μόνων στραμμένο προς το επάνω. Εάν πρόκειται να γίνει σφραγισ, θα πρέπει να γίνει σε αυτό το χρονικό σημείο της επέμβασης, τοποθετώντας ένα ράμμα όπως το MONOCRYL 2-0 ή το επικαλυμμένο ράμμα Coated VICRYL 2-0 στην κορυφή του κόλπου και περιτονίας το μέσο της κορυφαίας γωνιάδας του εμφυτεύματος πλέγματος. Η σφραγισ μπορεί να γίνει σε αυτό το χρονικό σημείο ή αφού τοποθετηθούν οι μόνες. Η σφραγισ της περιφερικής θάλακας του εμφυτεύματος πλέγματος είναι προαιρετική και μπορεί να γίνει με ένα ράμμα όπως το MONOCRYL 2-0 ή το επικαλυμμένο ράμμα Coated VICRYL 2-0.

Χρησιμοποιώντας τον πρόσθιο εισαγωγέα, υποστηρίξτε τους μόνες του εμφυτεύματος πλέγματος στο δεξιά και τον αριστερό δίαυλο που δημιουργήθηκε από το διαχωρισμό πρόσθια και επάνω από την ισχιακή άκρη (όπως περιγράφεται παραπάνω). **ΣΗΜΕΙΩΣΗ: Τα σωστά άκρα του πρόσθιου εισαγωγέα έχουν αναστραφεί σε αντίθετες κατευθύνσεις και σε κάθε άκρη υπάρχουν βέλη που υποδεικνύουν την κατεύθυνση τοποθέτησης.** Με το βέλος να δείχνει προς τη δεξιά πλευρά της ασθενούς, εισαγάγετε το άκρο του πρόσθιου εισαγωγέα μέσα στο θύλο του ιστού του εμφυτεύματος πλέγματος (βλ. εικόνα 8Β). Στη δεξιά πλευρά της ασθενούς. **ΣΗΜΕΙΩΣΗ: Η σφραγισ επιπλέοντας έλξης ενδέχεται να βοηθήσει ώστε να παραμείνει το θύλο στο φορτίο εισαγωγέα.** Διατηρήστε τον πρόσθιο εισαγωγέα σε κατακόρυφη θέση, έτσι ώστε το κυρτό τμήμα των εργαλείων να βρίσκεται απέναντι από το οπίσθιο κολπικό τοίχωμα. Στη συνέχεια, κατευθύνετε τον πρόσθιο εισαγωγέα, με φορτωμένο τον μόνον, προς το δίαυλο που δημιουργήθηκε προηγουμένως στον υ

παράλληλη πλευρά. Αυτό επιτυγχάνεται τοποθετώντας το τμήμα του πρόσθιου εισαγωγέα με τη λαβή σε κατεύθυνση προς τα επάνω και κατακόρυφη, έτσι ώστε το κυρτό άκρο και το θάλακο να κινούνται προς την ισχιακή άκρη. Αφού τοποθετηθεί, στρέψτε τη λαβή προς τα κάτω σε σχεδόν οριζόντια θέση, διατηρώντας τη λαβή σε επαφή με τον υπερίσθιακ μύρη. **ΣΗΜΕΙΩΣΗ: Η απόσπαση της ουροδόχου κύστης με ένα τυπικό χειρουργικό εργαλείο μπορεί να βοηθήσει κατά την αρχική τοποθέτηση στο δίαυλο. Εάν επιβ**
τε την αρχική τοποθέτηση του πρόσθιου εισαγωγέα έναντι των μεγάλων χειλίδων στην αντιπροσάλληλη πλευρά, προτού χρησιμοποιήσετε τη λαβή. Οδηγίστε ελαφρώς προς τα επάνω, διασφαλίζετε ότι τα θάλακα των μόνων έχουν τοποθετηθεί σωστά και ότι το κορυφαίο τμήμα του εμφυτεύματος πλέγματος θα εφαρμόσει στην κορυφή του κόλπου. **ΣΗΜΕΙΩΣΗ: Εάν αισθανθείτε αντίσταση κατά τη διάρκεια της εισαγωγής των υ των, προσδώ σε την αίσθηση συνεχίστε. Εάν συνεχίστε την προσπάθεια του εισαγωγέα υπό αντιστά**
τε
τος ή εισαγωγή πέραν του ενδεικνυόμενου σημείου, με αποτέλεσμα
ιστών.

Για την σφραγισ του πρόσθιου εισαγωγέα, επαναφέρετε τη λαβή στην κατακόρυφη θέση προτού την αποσύρετε, αφήνοντας τον μόνον μέσα στο δίαυλο. **ΣΗΜΕΙΩΣΗ: Εισαγάγετε τον πρώτο μόνον πλήρως. ΣΗΜΕΙΩΣΗ: Εάν ο πρόσθιος εισαγωγέας αναστραφεί προς τα έτω προτού μετα**
τας του εμφυτεύματος πλέγματος, ο μόνον θα πρέπει να αφαιρεθεί, να επανορθωθεί και ν
ισωθεί. Επανελαβετέ τη διαδικασία στην αντίθετη πλευρά της ασθενούς, γυρίζοντας τον πρόσθιο εισαγωγέα και εισάγοντας το άκρο, με το βέλος να δείχνει προς την αριστερή πλευρά της ασθενούς, μέσα στο έσω θάλακο. Η εικόνα 8D δείχνει και τους δύο μόνες τοποθετημένους. **ΣΗΜΕΙΩΣΗ: τή την τοποθέτηση του δεύτερου μόνου, προσέξτε ώστε να αποφευχθεί η μετακίνηση του εμφυτεύματος πλέγματος και βεβαιωθείτε ότι το εμφύτευμα πλέγματος ΔΕΝ έχει αναστραφεί.**

Τοποθετήστε χαλαρά το σώμα του εμφυτεύματος πλέγματος επάνω από τον υποκείμενο κολπικό ιστό. Θα πρέπει να αποφευχθεί η αναδίπλωση ή η συστροφή του σώματος και των μόνων. Το σώμα του εμφυτεύματος πλέγματος ενδέχεται να πρέπει να αποκλειστεί, ανάλογα με τις διαστάσεις του κόλπου ή το μέγεθος της πλευρικής συστολής. Το κολπικό επιθήλιο μπορεί να αποκλειστεί, αλλά θα πρέπει να αποφεύγεται υπερβολική σφύριση του. Κλείστε το επιθήλιο επάνω από το εμφύτευμα πλέγματος, χωρίς να χρησιμοποιήσετε αλληλοσυνδεδεμένο ράμμα (όπως περιγράφεται παραπάνω, βλ. εικόνα 8Ε). Η τελική τοποθέτηση του εμφυτεύματος πλέγματος στο πρόσθιο διαμέρισμα φαίνεται στην εικόνα 8Ε.

ΣΗΜΕΙΩΣΗ: Ιωθετέ ότι επιτυγχάνεται αμόσσηση πριν και κατά τη διάρκεια της σύγκλεισης των κολπικών τομών.

Κλείστε τις κολπικές τομές χωρίς αλληλοσυνδεδεμένο ράμμα ή ράμμα σχήματος οκτώ. Με τον τρόπο αυτό, αποφεύγεται η απορρόφηση του κολπικού επιθηλίου κατά μήκος των γωνιών των τομών και μειώνεται η διάβρωση του πλέγματος. Η σύγκλειση του επιθηλίου γίνεται κατά πρότυπη σε 2 σπλάξεις, ώστε να προκύψει μια σχετικά σιμωμένη γραμμή σφραγισ στο σημείο της κολπικής τομής. Κλείστε τη διάβρωση σπλάξ με μια συνηθ, υποεπίσθιακ, μη-αλληλοσυνδεδεμένη σφραγισ με ένα ράμμα όπως το MONOCRYL 2-0 ή το αντιβιοτικό-απορροσώσιμο ράμμα MONOCRYL™ Plus (πολυλυσκροπρόνη 25) 2-0. Στη συνέχεια, κλείστε το επιθήλιο με μια μη-αλληλοσυνδεδεμένη, συνηθ, σφραγισ αναστραμμένο ράμμα (Coated VICRYL™ Plus (πολυλυσκροπρόνη 910) 2-0). **ΣΗΜΕΙΩΣΗ: Τοποθετήστε το εμφύ**
ς στα άνω 2/3 του κόλπου, φροντίζοντας να το αποκλείετε εάν εκτείνεται πέραν των 2/3. Εάν δεν έχει γίνει ήδη, συνιστάται κυστεοσκόπηση, ώστε να αποκλειστεί το ενδεχόμενο τραυματισμού της ουροδόχου οδού.

Ενυδατωθεί, μπορεί να πραγματοποιηθεί σύγκλειση του κολπικού τοιχώματος σε μία σπλάξ. Μπορεί να χρησιμοποιηθεί μια συνηθ, μη αλληλοσυνδεδεμένη σφραγισ αναστραμμένου σχήματος ή διακοπόμενης σφραγισ, με ράμμα όπως το επικαλυμμένο Coated VICRYL 2-0 ή το επικαλυμμένο Coated VICRYL Plus 2-0.

Οπίσθια κοιλιακή αποκατάσταση

Όταν απαιτείται ενίσχυση μόνον του οπίσθιου κοιλιακού τοιχώματος, χρησιμοποιήστε μόνο το σύστημα αποκατάστασης οπίσθιου ελάσματος GYNECARE PROSOMA. Αυτό περιλαμβάνει 1 εμφύτευμα πλέγματος και έναν ελκτικό σχεδιασμένο οπίσθιο εισαγωγέα για χρήση στην οπίσθια κοιλιακή αποκατάσταση. Αφού πραγματοποιήσετε τις απαιτούμενες κοιλιακές τομές και το διαχωρισμό του ιστού, δημιουργήστε διαύλους στον ιστό του οπίσθιου διαμερίσματος, για να τοποθετήσετε σε αυτούς τους μόνες του εμφυτεύματος πλέγματος. **ΣΗΜΕΙΩΣΗ** *Το εισαγωγέας δεν πρέπει να κείται για το διαχωρισμό ιστού.*

Οπίσθιος κοιλιακός διαχωρισμός και διάνοιξη διαύλων

Διαχωρίστε το οπίσθιο κοιλιακό επιθήλιο από τον προ-αρθικό ιστό. Όπως και το πρόσθιο κοιλιακό τοίχωμα, το οπίσθιο κοιλιακό τοίχωμα θα πρέπει να διαχωριστεί σε όλο το πάχος του. Ο διαχωρισμός αυτός θα πρέπει να διευκολύνεται από υποεπιθηλιακό υδραδιαχωρισμό. Συνεχίστε το διαχωρισμό του ιστού πλευρικά, σε κάθε πλευρά, προς τους ανελκυστές μύες του πριεκτού, στο επίπεδο της γαστρικής άκρας. Στη συνέχεια, συνεχίστε το διαχωρισμό διαμέσου καθέμιας από τις στήλες του αρθού και προς καίεναν από τους ιερωνοτιώδεις συνδέσμους, αλλά όχι άμεσα του ανώτερου, δημιουργώντας διαύλους μέσω αυτών οποίους θα τοποθετηθούν οι μόνες του εμφυτεύματος πλέγματος. βλ. εικόνα 9A.

Η αντιμετώπιση τυχόν προεπάρχουσας εντερικής είναι προαιρετική αλλά, εάν πραγματοποιηθεί, μπορεί να γίνει σε αυτό το στάδιο, σύμφωνα με την προτιμώμενη τεχνική του χειρουργού.

Εάν η περιτοναϊκή κοιλότητα έχει αναχθεί κατά τη διάρκεια του πρόσθιου ή του οπίσθιου διαχωρισμού, θα πρέπει να γίνει σύγκλειση της πύας από την τοποθέτηση του πλέγματος.

Τοποθέτηση του οπίσθιου εμφυτεύματος πλέγματος

Δεν απαιτείται πτύχωση του προ-αρθικού ιστού. Ωστόσο, εάν πραγματοποιηθεί πτύχωση του προ-αρθικού ιστού, πτυγχάνεται μόνο το κεντρικό τμήμα του προ-αρθικού ιστού. Με αυτό τον τρόπο, η περιοχή όπου γίνεται ο διαχωρισμός δεν γίνεται ποτέ στενή. Τοποθετήστε το εμφύτευμα πλέγματος εκτός από τον προ-αρθικό ιστό, με τα θυλακία των μόνων στραμμένα προς τα πάνω. Εάν πρόκειται να γίνει χειρουργική, θα πρέπει να γίνει σε αυτό το χρονικό σημείο της επέμβασης, τοποθετώντας ένα ράβμα όπως το MONOCRYL 2-0 ή το επικαλυμμένο ράβμα Coated VICRYL 2-0 στην κορυφή του κόλλου και περνώντας το μέσω της κορυφαίας γλωττίδας του εμφυτεύματος πλέγματος. Η χειρουργική μπορεί να γίνει σε αυτό το χρονικό σημείο ή αφού τοποθετηθούν οι μόνες. Η χειρουργική της περιφερικής αλλαγής του εμφυτεύματος πλέγματος είναι προαιρετική και μπορεί να γίνει με ράβμα όπως το MONOCRYL 2-0 ή το επικαλυμμένο ράβμα Coated VICRYL 2-0.

Χρησιμοποιώντας τον οπίσθιο εισαγωγέα, τοποθετήστε τους μόνες του εμφυτεύματος πλέγματος στο δεξιό και τον αριστερό έλκτο που δημιουργήθηκε από το διαχωρισμό προς καίεναν από τους ιερωνοτιώδεις συνδέσμους (όπως περιγράφεται παραπάνω). Χρησιμοποιήστε τον οπίσθιο εισαγωγέα χρησιμοποιώντας ένα ευθύ βελονοκότυπο/οδηγό, όπως φαίνεται στην εικόνα 9B. **ΣΗΜΕΙΩΣΗ** *Τήστε το άκρο του βελονοκότυπου/οδηγού μέσα στο ευθύ άκρο του οπίσθιου εισαγωγέα.* Βεβαιωθείτε ότι ο συνδεδεμένος οπίσθιος εισαγωγέας είναι ευθυγραμμισμένος με τη λαβή του βελονοκότυπου/οδηγού. Εισαγάγετε το άκρο του οπίσθιου εισαγωγέα μέσα στο θυλακίο του μόνου, στη δεξιά πλευρά της στήλης (βλ. εικόνα 9B). Στη συνέχεια, κατεβάζετε τον οπίσθιο εισαγωγέα, με φορτωμένο τον μόνου, μέσα στο θυλακίο που δημιουργήθηκε προηγουμένως στον ιστό (βλ. εικόνα 9C), διατηρώντας τη λαβή του βελονοκότυπου/οδηγού σε όρθια θέση. Προχωρήστε στην εισαγωγή ολόκληρου του μόνου μέσα στο έλκτο, έτσι ώστε η βάση του μόνου να συνστήσει το επάνω άκρο της περιτοναϊκού διαχωρισμού. **ΣΗΜΕΙΩΣΗ: Εισαγάγετε τον πρώτο μόνου πλήρως. Εάν ο εισαγωγέας αναστρέφει προς τα έξω πρώτου μεταφερθεί στο στόχο ο ή**

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**6O** **6P** **6Q** **6R** **6S** **6T** **6U** **6V** **6W** **6X** **6Y** **6Z** **7A** **7B** **7C** **7D** **7E** **7F** **7G** **7H** **7I** **7J** **7K** **7L** **7M** **7N** **7O** **7P** **7Q** **7R** **7S** **7T** **7U** **7V** **7W** **7X** **7Y** **7Z** **8A** **8B** **8C** **8D** **8E** **8F** **8G** **8H** **8I** **8J** **8K** **8L** **8M** **8N** **8O** **8P** **8Q** **8R** **8S** **8T** **8U** **8V** **8W** **8X** **8Y** **8Z** **9A** **9B** **9C** **9D** **9E** **9F** **9G** **9H** **9I** **9J** **9K** **9L** **9M** **9N** **9O** **9P** **9Q** **9R** **9S** **9T** **9U** **9V** **9W** **9X** **9Y** **9Z** **10A** **10B** **10C** **10D** **10E** **10F** **10G** **10H** **10I** **10J** **10K** **10L** **10M** **10N** **10O** **10P** **10Q** **10R** **10S** **10T** **10U** **10V** **10W** **10X** **10Y** **10Z** **11A** **11B** **11C** **11D** **11E** **11F** **11G** **11H** **11I** **11J** **11K** **11L** **11M** **11N** **11O** **11P** **11Q** **11R** **11S** **11T** 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Διόγκωση του μπουλονιού

Αφού σφραγίσετε τη ΔΚΥ στη θέση της, προσομοίστε την παρεχόμενη σύριγγα των 50 ml, περιστρέφοντάς την ώστε να ασφαλιστεί επάνω στη βαλβίδα του μπουλονιού. **ΣΗΜΕΙΩΣΗ: Μετά την τοποθέτηση της ΔΚΥ, είναι απαραίτητη η τοποθέτηση ενός καθετήρα για να αποσφραγιστεί κατά τη διάρκεια της ΔΚΥ.** Μετά από τη διόγκωση με ένα μικρό όγκο αέρα από το περιβάλλον (βλ. εικόνα 16), φιλάφιστε με ένα δάκτυλο όλο το μήκος του μπουλονιού για να βεβαιωθείτε ότι το μπουλόνι έχει εκπτυχθεί και εφαρμόσει πλήρως στον κόλπο. Αφού επιβεβαιώσετε την έκπτυξη, αφαιρέστε το δάκτυλο και συνεχίστε τη διόγκωση του μπουλονιού έως ότου μόνο το άκρο του δακτύλου να χωράει άνετα στο άνοιγμα, ανάμεσα στο μπουλόνι και στο κοιλιακό τοίχωμα. Κατά τη διάρκεια της διόγκωσης συνιστάται η σταθεροποίηση της ΔΚΥ. Το εγκεκριμένο μολύβι εμπίπτει στη εφαρμογή του εμφυτεύματος πλεγματος επάνω στο κοιλιακό τοίχωμα. Ο άκρος του αέρα που απαιτείται για την ασφαλή διόγκωση του μπουλονιού θα ποικίλλει από ασθενή σε ασθενή. **ΣΗΜΕΙΩΣΗ: Ο μέγιστος όγκος διόγκωσης του μπουλονιού δεν πρέπει να υπερβαίνει τα 90 ml.** Αφού διαγκωθεί επαρκώς το μπουλόνι, αφαιρέστε τη σύριγγα από τη βαλβίδα περιστρέφοντάς την. Η γραμμή διόγκωσης του μπουλονιού πρέπει να εξέλθει από τον κόλπο ώστε να επικαλυφθεί στο μπρο της ασθενούς. Το πόμολο πρέπει να ασφαλιστεί στη βαλβίδα του μπουλονιού, ώστε να διωσφολιστεί η διατήρηση του επιθυμητού όγκου αέρα στο μπουλόνι (βλ. εικόνα 7). **ΣΗΜΕΙΩΣΗ: Μη αφήνετε υπερβολικά το πόμολο.** Εάν χρειαστεί, το μπουλόνι μπορεί να ρυθμιστεί αργότερα, χρησιμοποιώντας μια τυπική σύριγγα για την αύξηση ή τη μείωση του αέρα που περιέχεται στο μπουλόνι. Σε οποιαδήποτε στιγμή, το μπουλόνι μπορεί να ψηλαφηθεί ή να ελεγχθεί οπτικά για να επιβεβαιωθεί ότι διατηρεί επαρκή διόγκωση. **ΣΗΜΕΙΩΣΗ: Καθώς κινείται η ασθενής, το μπουλόνι θα σταθεροποιηθεί στην κατωτερή κατεύθυνση και ενδέχεται να ιμειώνεται. Αυτό είναι φυσιολογικό.**

ΣΗΜΕΙΩΣΗ: Μην αφαιρείτε το μπουλόνι α τη ΔΚΥ πριν από τη χρήση.

ΣΗΜΕΙΩΣΗ: Μη διογκώνετε το μπουλόνι πριν από την εγκατάσταση στον κόλπο.

ΣΗΜΕΙΩΣΗ: Μετά τη διόγκωση του μπουλονιού, εάν οι υπές ραμμάτων της ΔΚΥ έχουν μετακινιστεί περισσότερο από 1cm επάνω από το δάκτυλο του υμένα ή εάν υπάρχουν κί και εάν απαιτείται, επανανοθετήστε τη ΔΚΥ ή ρυθμίστε εκ νέου το μέγεθός της.

ΣΗΜΕΙΩΣΗ: Εάν παρατηρήσετε τυχόν όπες στο μπουλόνι ή εάν αρχίσει να διογκώνεται, ΜΗΝ το χρησιμοποιείτε. Θα πρέπει να αφαιρεθεί από τη ΔΚΥ και να αποσφραγιστεί κατάλληλα. Χρησιμοποιήστε τυ τη θέση του μπουλονιού.

ΣΗΜΕΙΩΣΗ: Εάν αποκαλυφθεί από τη ΔΚΥ το βόθριο σύνδεσης του μπουλονιού, αιώστε τα ξανά στη θέση του.

ΣΗΜΕΙΩΣΗ: Μη στερεώνετε τη γραμμή διόγκωσης του μπουλονιού μέσα στον κόλπο.

ΣΗΜΕΙΩΣΗ: Για να αποφύγετε την πρόκληση βλάβης, ποτέ μην ασκείτε υπερβολική δύναμη κάρφης, τάσης ή περιστροφής στη γραμμή διαστολής.

ΣΗΜΕΙΩΣΗ: Μην τοποθετείτε γότζες όταν έχει ήδη τοποθετηθεί μπουλόνι.

Αφαίρεση μπουλονιού από τη ΔΚΥ

Χρησιμοποιώντας μια τυπική σύριγγα, αδειάστε πλήρως και αφαιρέστε το μπουλόνι, 1 ημέρα μετά την εμφύσηση, αφήνοντας τη ΔΚΥ στη θέση της. **ΣΗΜΕΙΩΣΗ: Μην αφήνετε το μπουλόνι μέσα στον κόλπο επί περισσότερο από 1 ημέρα.**

1) Αφαιρέστε το πόμολο από τη βαλβίδα του μπουλονιού.

2) Προσομοίστε μια τυπική σύριγγα των 50 ml (ή μεγαλύτερη) στη βαλβίδα του μπουλονιού και αδειάστε το πλήρως (βλ. εικόνα 17). Είναι σημαντικό να αποσυρθείτε πλήρως το μπουλόνι επιχερήστες να το αφαιρέσετε από τη ΔΚΥ. **ΣΗΜΕΙΩΣΗ: Το πλήρες αποσυρμένο μπουλόνι θα προκαλέσει την πρόκληση του ερβάλου της σύριγγας, μετά την αφαίρεση αλλού του αέρα.**

3) Αφαιρέστε τη σύριγγα.

4) Στη συνέχεια, το μπουλόνι μπορεί να διαχωριστεί από τη ΔΚΥ και να αφαιρεθεί από την ασθενή, έλκοντας ελαφρά τη γραμμή διόγκωσης προς την οριζόντια κατεύθυνση, σε ένα σημείο κοντά στο βόθριο σύνδεσης του μπουλονιού, εφαρμόζοντας ταυτόχρονα με ένα δάκτυλο ελαφρά τάση προς την αντίθετη κατεύθυνση από το περιφερικό άκρο της ΔΚΥ. βλ. εικόνα 18.

ΣΗΜΕΙΩΣΗ: Μην αποσύρετε το μπουλόνι εάν δεν έχει αποδοκιμασθεί πλήρως και εάν αισθανθείτε οποιαδήποτε αντίσταση. Εάν αισθανθείτε αντίσταση, προσομοίστε την απία προτού συνεχίσετε. Εάν συνεχίσετε να προωθείτε ή να ανασύρετε το μπουλόνι υπό αντίσταση, ταυτόχρονα της ΔΚΥ και/ή τραύμα στους ιστούς της κοιλιακής κοιλότητας. Για να βεβαιωθείτε ότι ο αέρας έχει αφαιρεθεί πλήρως, επανανοθετήστε τη σύριγγα αφαιρέστε όλα τον αέρα προτού συνεχίσετε με την αφαίρεση του μπουλονιού.

Αφαίρεση της ΔΚΥ από την ασθενή

Αφαιρέστε τη ΔΚΥ από την ασθενή περίπου 3 έως 4 εβδομάδες μετά τη χειρουργική επέμβαση, αφού έχει ελπίσει επαρκής αποκάλυψη. Στο χρόνο αυτό, τα απορροφώσιμα ράμματα ενδέχεται να έχουν διαλυθεί ή να μην έχουν αρκετή αντοχή επεκτάσει, έτσι ώστε να επιτρέψουν την αφαίρεση της ΔΚΥ χωρίς αντίσταση από τα ράμματα. **ΣΗΜΕΙΩΣΗ: Μην αφήνετε το πόμολο να κινείται και τα δύο ράμματα για την αφαίρεση. ΣΗΜΕΙΩΣΗ: Μην αφήνετε τη ΔΚΥ μέσα στον κόλπο επί περισσότερο από τον κοιλιακό τοίχωμα, όπως φαίνεται στην εικόνα 19.**

Παραγγειρητική φροντίδα

Μπορεί να χορηγηθεί προφυλακτική αντιβιοτική αγωγή σύμφωνα με τη συνήθη πρακτική του χειρουργού. Η χορήγηση αντιβιοτικών μπορεί να συνεχιστεί μετεγχειρητικά, ανάλογα με την πρόληψη του χειρουργού. Μπορεί να χρησιμοποιηθεί προφυλακτική θρομβοεμβολική αγωγή.

Ο χειρουργός θα πρέπει να εξηγήσει ότι ο στόχος της ΔΚΥ, η οποία παραμένει στον κόλπο για διάστημα έως και τεσσάρων εβδομάδων μετά τη χειρουργική επέμβαση, είναι να υποστηρίξει τον κόλπο επάνω στο πλέγμα κατά τη διάρκεια της περιόδου επουλώσεως. Η ασθενής θα πρέπει να ενημερωθεί ότι η ΔΚΥ θα αφαιρεθεί κατά τη διάρκεια ενός μετεγχειρητικού ελέγχου, περίπου 4 εβδομάδες μετά την επέμβαση. Η ασθενής θα πρέπει να ενημερωθεί ότι μετεγχειρητικά ενδέχεται να εμφανιστούν κοιλιακές εκκρίσεις (και ότι η ΔΚΥ μπορεί να μετακινηθεί ελαφρά προς τα κάτω). Εάν η ασθενής αισθανθεί ότι η ΔΚΥ έχει μετακινηθεί προς τα κάτω, μπορεί να την αιώσει μαλακά προς τα πάνω, σε μια πιο άνετη θέση. Παρόλα αυτά, εάν η ΔΚΥ προκαλεί σημαντική δυσφορία, η ασθενής θα πρέπει να γνωρίζει ότι πρέπει να επικοινωνήσει με τον ιατρό της.

Μετά την έξοδο από το νοσοκομείο, θα πρέπει να δοθούν οδηγίες στην ασθενή να αποφύγει την έντονη δραστηριότητα επί μια περίοδο 3 έως 4 εβδομάδων. Σε αυτό το χρονικό διάστημα οι πυελικοί ιστοί θα έχουν ενσωματωθεί στο εμφύτεμα πλεγματος και η ασθενής θα μπορεί να επιστρέψει στις δραστηριότητες της κανονικής καθημερινής ζωής. Θα πρέπει να γίνει σύσταση στην ασθενή να αποφύγει τη σεξουαλική επαφή επί τουλάχιστον 6 εβδομάδες μετά τη χειρουργική επέμβαση. Ο ιατρός μπορεί να συστήσει αδείξεις πυελικού εδάφους οποιαδήποτε στιγμή μετά τη χειρουργική επέμβαση.

ΑΠΟΔΟΣΗ

Μελέτες σε ζώα καταδεικνύουν ότι η εμφύτευση πλεγματος GYNECARE GYNEMESH PS προκαλεί ελάχιστη έως ελαφρά φλεγμονώδη αντίδραση, η οποία είναι παροδική και ακολουθείται από την ενσωμάτωση ενός λεπτού ενώσιμου στρώματος ιστού, το οποίο μπορεί να αναπτυχθεί διαμέσου των διακένων του πλεγματος, ενσωματώνοντας έτσι το πλέγμα στον παρακείμενο ιστό. Το πλέγμα παραμένει μαλακό και εύπλαστο, ενώ η φυσιολογική επώλωση του τραύματος δεν επηρεάζεται εμφανώς. Το υλικό δεν απορροφάται, ούτε υφίσταται αποδόμηση ή εξασθένιση από τη δράση των ενζύμων του ιστού.

ΑΝΤΕΝΔΕΞΕΙΣ

- Όταν το πλέγμα GYNECARE GYNEMESH PS χρησιμοποιείται σε βρέφη, σε παιδιά, σε εγκύους ή σε γυναίκες που σκοπεύουν να τεκνοποιήσουν στο μέλλον, ο χειρουργός θα πρέπει να γνωρίζει ότι αυτό το προϊόν δεν θα εκτοπίσει σε σημαντικό βαθμό κατά τη φυσιολογική ανάπτυξη της ασθενούς.
- Το σύστημα GYNECARE PROSIMA δεν θα πρέπει να χρησιμοποιείται σε περιπτώσεις εγκυμοσύνης, σπασμώδους φλεγμονής ή νεοπλασίας του κόλπου, του τραχήλου ή της μήτρας.

ΠΡΟΕΙΔΟΠΟΙΗΣΕΙΣ ΚΑΙ ΠΡΟΦΥΛΑΞΕΙΣ

- Πριν από τη χρήση των συστημάτων GYNECARE PROSIMA, οι ιατροί που τα χρησιμοποιούν θα πρέπει να είναι εξοικειωμένοι με τις χειρουργικές διαδικασίες και τεχνικές που σχετίζονται με την αποκατάσταση πυελικού εδάφους και τη χρήση μη απορροφήσιμων πλεγμάτων.
- Η χρήση του συστήματος GYNECARE PROSIMA δεν έχει αξιολογηθεί πλήρως σε ασθενείς με πρόπτωση πυελικού οργάνου σταδίου IV. Για το λόγο αυτό, η χρήση του σε αυτές τις ασθενείς δεν συνιστάται.
- Κατά τη χρήση του συστήματος GYNECARE PROSIMA, όπως και κατά την αντιμετώπιση μολυσμένων ή επιμολυσθέντων τραυμάτων, ακολουθήστε τις γενικά αποδεκτές χειρουργικές πρακτικές.
- Μη χρησιμοποιείτε το σύστημα GYNECARE PROSIMA εάν πιστεύετε ότι το σημείο της χειρουργικής επέμβασης ενδέχεται να έχει υποστεί κοίμηση ή ραμνωση. Εάν το εμφύτεμα πλεγματος ή η διάταξη ΔΚΥ-μπουλονιού χρησιμοποιηθεί σε επιμολυσμένες περιοχές, θα πρέπει να γνωρίζετε ότι τυχόν εισκόλληση λοίμωξης ενδέχεται να απαιτήσει την αφαίρεσή τους.
- Κατά την επέμβαση, θα πρέπει να γίνει σύσταση στην ασθενή να αποφύγει την συνολική βάρους κοιλιά την άσκηση (π.χ. ποδηλασία, τρέξιμο) επί 3 έως 4 εβδομάδες και τη σεξουαλική επαφή επί 6 εβδομάδες, μέχρις ότου ο ιατρός διαπιστώσει ότι μπορεί να επανέλθει στις κανονικές της δραστηριότητες.
- Μην αφήνετε τη ΔΚΥ μέσα στον κόλπο επί περισσότερο από 4 εβδομάδες.
- Μην αφήνετε το μπουλόνι μέσα στον κόλπο επί περισσότερο από 1 ημέρα.
- Τα εξαρτήματα του συστήματος GYNECARE PROSIMA δεν προορίζονται για χρήση με συσκευές άλλες από αυτές που αναφέρονται σε αυτό το ένθετο συσκευασίας.
- Αποφύγετε την εφαρμογή υπερβολικής τάσης στο εμφύτεμα πλεγματος κατά το χειρισμό του.
- Χρησιμοποιήστε το σύστημα GYNECARE PROSIMA με προσοχή και λαμβάνοντας υπόψη την ανατομία της ασθενούς, προκειμένου να αποφύγετε τυχόν βλάβη σε όργανα, νεύρα, στην ουροδόχο κύστη και στο έντερο, καθώς και διατήρηση του κοιλιακού τοιχώματος. Η σωστή χρήση των εξαρτημάτων του συστήματος GYNECARE PROSIMA θα ελαχιστοποιήσει τους κινδύνους.
- Η διόγκωση του μπουλονιού πρέπει να γίνεται μόνο με αέρα από το περιβάλλον.
- Η φήληση θα επιβεβαιώσει ότι δεν υπάρχουν διαρροές αέρα από το μπουλόνι μετά τη διόγκωση. Πλήρης απόλυση της διόγκωσης ενδέχεται να περιορίσει την αποτελεσματικότητα του μπουλονιού.
- Το τοίχωμα του μπουλονιού είναι λεπτό, έτσι ώστε να επιτυγχάνονται οι επιθυμητές ιδιότητες. Διατρήσεις, κοψίματα, εκκοπές, σύλληψη ή υπερκατάπληξη ενδέχεται να οδηγήσουν σε οποιαδήποτε διόγκωση. Το μπουλόνι μπορεί να διατηρηθεί εύκολα από βελόνα ή νυστέρη ή να διαρραγεί από χειρισμό με ένα συμβαλό εργαλείο. Κατά το χειρισμό του πρέπει να είστε προσεκτικοί ώστε να αποφύγετε τέτοια περιστατικά. Ένα μπουλόνι που έχει υποστεί βλάβη δεν πρέπει να χρησιμοποιείται. Αφαιρέστε το και χρησιμοποιήστε γότζες.
- Οι μέγιστοι όγκος διόγκωσης του μπουλονιού είναι 90 ml. Μη διογκώνετε υπερβολικά το μπουλόνι. Υπερβολική διόγκωση του μπουλονιού ενδέχεται να προκαλέσει δυσφορία στην ασθενή, νέκρωση ιστών, μετεγχειρητική διάρρηξη κοιλιακού τραύματος ή αβέβαιη αφαίρεση.
- Μη χρησιμοποιείτε τα συστήματα GYNECARE PROSIMA σε ασθενείς οι οποίες ακολουθούν αντιπηκτική θεραπεία.
- Ενδέχεται να εμφανιστεί αιμορραγία μετεγχειρητικά. Εξετάστε την ασθενή για οποιαδήποτε συμπτώματα ή σημεία πριν από την έξοδο της από το νοσοκομείο.
- Πρέπει να ζητηθεί από την ασθενή να επικοινωνήσει αμέσως με τον χειρουργό εάν εμφανιστεί ασυνήθιστος πόνος, αιμορραγία ή άλλα προβλήματα.
- Μολονότι οι πιθανότητες τραυματισμού της ουροδόχου κύστης με αυτή την τεχνική είναι λίγες, συνιστάται η διενέργεια κυστεοσκοπικής.
- Μολονότι οι πιθανότητες τραυματισμού του ορθού με αυτή την τεχνική είναι λίγες, απαιτείται η διενέργεια δακτυλικής εξέτασης.
- Μην στερεώνετε το εμφύτεμα πλεγματος GYNECARE GYNEMESH PS με συνδετήρες, κλίπ ή σφιγκτήρες, καθώς ενδέχεται να προκαλέσει μηχανική βλάβη στο πλέγμα.
- Το εμφύτεμα πλεγματος δεν πρέπει να βυθίζεται στο κάτω τριτημώριο του κόλπου. Εάν χρειαστεί, αποκόψτε το εμφύτεμα πλεγματος έως τη συμβολή του κάτω με το μέσο τριτημώριο του κόλπου.
- Μπορεί να χορηγηθεί προφυλακτική αντιβιοτική αγωγή, σύμφωνα με τη συνήθη πρακτική του χειρουργού.

ΑΝΕΠΙΘΥΜΗΤΕΣ ΑΝΤΙΔΡΑΣΕΙΣ

- Οι δυναμικές ανεπιθύμητες αντιδράσεις είναι εκείνες που σχετίζονται συνήθως με χειρουργικούς εμφυτεύματα υλικού και περιλαμβάνουν την αυξημένη πιθανότητα λοίμωξης, τη φλεγμονή, το σχηματισμό συμφύσεων, το σχηματισμό ουρηθρίων, τη διάρρηξη, την εξώθηση και τη δημιουργία υαλινών που προκαλούν συστολή του εμφυτεύματος.
- Οι δυναμικές ανεπιθύμητες αντιδράσεις είναι εκείνες που σχετίζονται με τις διαδικασίες αποκατάστασης πρώτων πυελικών οργάνων, συμπεριλαμβανομένου του πόνου κατά τη σεξουαλική επαφή και του πυελικού τόνου. Αυτά μπορεί να λυθούν από μόνα τους με την πάροδο του χρόνου.
- Κατά το διαχωρισμό ιστών ή την τοποθέτηση του πλεγματος ενδέχεται να προκύψει διάτρηση, ρήξη ή τραυματισμός σπείνης, νεύρων, της ουροδόχου κύστης, της ουρήθρας ή του εντέρου, οι οποίες πιθανόν να απαιτήσουν χειρουργική αποκατάσταση.
- Οι διαχωρισμοί ιστών για τις διαδικασίες αποκατάστασης πυελικού εδάφους ενδέχεται να διαταράξουν την κανονική αγωγή για χρονικό διάστημα που μπορεί να ποικίλλει.

ΣΤΕΙΡΟΤΗΤΑ

Τα συστήματα GYNECARE PROSIMA αποστειρώνονται με αιθυλενοξείδιο. ΜΗΝ ΕΠΑΝΑΠΟΣΤΕΙΡΩΝΕΤΕ οποιοδήποτε τμήμα του συστήματος GYNECARE PROSIMA. ΜΗΝ ΕΠΑΝΑΧΡΗΣΙΜΟΠΟΙΕΙΤΕ οποιοδήποτε τμήμα του συστήματος GYNECARE PROSIMA. Η επαναχρησιμοποίηση αυτής της συσκευής (ή μερών αυτής της συσκευής) είναι δυνατό να προκαλέσει κίνδυνο αποδόμησης του προϊόντος και διασποράς μολύνσης, η οποία ενδέχεται να οδηγήσει σε λοίμωξη ή μετάδοση αιματογενώς μεταδιδόμενων παθογόνων μικροοργανισμών σε ασθενείς και χρήστες. Μην το χρησιμοποιείτε εάν η συσκευή έχει ανοίξει ή έχει υποστεί ζημιό. Απορρίψτε όλα τα εξαρτήματα του συστήματος GYNECARE PROSIMA που ανοίχθηκαν αλλά δεν χρησιμοποιήθηκαν.








ΑΠΟΡΡΙΨΗ

Απορρίψτε τα εξαρτήματα του συστήματος GYNECARE PROSIMA και τη συσκευασία τους σύμφωνα με την πολιτική και τις διαδικασίες απόρριψης βιολογικά επικινδύνων υλικών και αποβλήτων του ιδρύματός σας.

ΦΥΛΑΞΗ

Συνιστάται να φυλάσσεται σε συνθήκες ελεγχόμενης θερμοκρασίας και σχετικής υγρασίας δωματίου (περίπου 25 °C, 60 % σχετική υγρασία), μακριά από υγρασία και άμεσες πηγές θερμότητας. Μην το χρησιμοποιείτε μετά την παρέλευση της ημερομηνίας λήξης.

Σύμβολα που χρησιμοποιούνται στις ετικέτες

<p> 0086 Σημάδι CE και αριθμός αναγνώρισης του Φορέα Κοινοποίησης. Το προϊόν είναι σύμφωνο με τις συνθήκες απαιτήσεις της Οδηγίας 93/42/EE που αφορά στις ιατρικές συσκευές.</p>	<p> Κατασκευαστής</p> <p> Μην επαναχρησιμοποιείτε/επαναστείρυνετε</p>
<p> Αριθμός Παρτίδας</p>	<p> Δείτε τις οδηγίες χρήσης</p>
<p> Ημερομηνία λήξης — έτος και μήνας</p>	<p> Μέθοδος αποστείρωσης — αιθυλενοξείδιο</p>

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Εξουσιοδοτημένος Αντιπρόσωπος

Johnson & Johnson Medical Limited
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Distributors • Distributører • Distributeurs • Tukkumyyjät • Distributeurs • Vertrieb durch •
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CH Johnson & Johnson AG
Rotzenbuehlstrasse 55
CH-8957, Spreitenbach

Manufactured for:

Gynecare 

ETHICON Women's Health & Urology
A division of ETHICON, INC.
a Johnson & Johnson company
Somerville, New Jersey 08876-0151



Reference to P21071

ETH.MESH.02341453

Christina Pramudji, M.D.

Page 1

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.,) Master File
PELVIC REPAIR SYSTEM) No. 2:12-MD-02327
PRODUCTS LIABILITY) JOSEPH R. GOODWIN
LITIGATION) U.S. DISTRICT JUDGE

THIS DOCUMENT RELATES TO)
THE FOLLOWING CASES IN WAVE)
1 OF MDL 200:)

JOY ESSMAN)
Case No. 2:12-cv-00277)

BARBARA A. HILL)
Case No. 2:12-cv-00806)

PAULA KRIZ)
Case No. 2:12-cv-00938)

BRENDA RIDDELL) ORAL DEPOSITION OF
Case No. 2:12-cv-00547) CHRISTINA PRAMUDJI, M.D.

SHARON CARPENTER) MARCH 23, 2016
Case No. 2:12-cv-00554)

MARY JANE OLSEN)
Case No. 2:12-cv-00470)

VIRGINIA WHITE)
Case No. 2:12-cv-00958)

SANDRA WOLFE)
Case No. 2:12-cv-00335)

MARIE SMITH (F/K/A BANKS))
Case No. 2:12-cv-01318)

SHERRY FOX)
Case No. 2:12-cv-00878)

LOIS DURHAM)
Case No. 2:12-cv-00760)

Christina Pramudji, M.D.

Page 2	Page 4
1 ELIZABETH BLYNN WILSON) Case No. 2:12-cv-01286) 2) 3 DAPHNE BARKER) Case No. 2:12-cv-00899) 4) 5 WENDY HAGANS) Case No. 2:12-cv-00783) 6) 7 MARIA EUGENIA QUIJANO) Case No. 2:12-cv-00799) 8) 9 SHARON BOGGS) Case No. 2:12-cv-00368) 10) 11 CAREY COLE) Case No. 2:12-cv-00483) 12) 13 CATHY WARLICK) Case No. 2:12-cv-00276) 14) 15 DONNA AMSDEN) Case No. 2:12-cv-00960) 16) 17 HEATHER LONG) Case No. 2:12-cv-01275) 18) 19 PENNY RHYNEHART) Case No. 2:12-cv-01119) 20) 21 NANCY JO WILLIAMS) Case No. 2:12-cv-00511) 22) 23 MARIA STONE) Case No. 2:12-cv-00652) 24) 25 TERRI KEY SHIVELY) Case No. 2:12-cv-00379) 26) 27 CHARLENE LOGAN TAYLOR) Case No. 2:12-cv-00376) 28) 29 TINA MORROW) Case No. 2:12-cv-00378) 30) 31 CAROL JEAN DIMOCK) Case No. 2:12-cv-004001)	1 APPEARANCES 2 3 4 FOR THE PLAINTIFFS: ANDREW N. FAES, ESQ. Wagstaff & Cartmell LLP 4740 Grand Avenue, Suite 300 Kansas City, Missouri 64112 816.701.1100 afaes@wcllp.com 7 8 9 FOR THE DEFENDANTS: WILLIAM M. GAGE, ESQ. Butler Snow, LLP 1020 Highland Colony Parkway, Suite 1400 Ridgeland, Mississippi 39157 601.948.5711 william.gage@butlersnow.com 12 13 ALSO PRESENT: 14 Ms. Tamara Vinson, Court Reporter 15 16 17 18 19 20 21 22 23 24
Page 3	Page 5
1 ORAL DEPOSITION OF CHRISTINA PRAMUDJI, M.D. 2 produced as a witness at the instance of the 3 PLAINTIFFS, and duly sworn, was taken in the 4 above-styled and numbered cause on the 23rd of March, 5 2016, from 1:20 p.m. to 4:25 p.m., before Tamara 6 Vinson, CSR in and for the State of Texas, reported by 7 machine shorthand, at the Westin-Houston Memorial 8 City, 945 Gessner Road, Houston, Texas, 77024, 9 pursuant to the Federal Rules of Civil Procedure and 10 the provisions stated on the record or attached 11 hereto. 12 13 14 15 16 17 18 19 20 21 22 23 24	1 INDEX 2 PAGE 3 Appearances.....3 4 5 CHRISTINA PRAMUDJI, M.D. 6 7 Examination by Mr. Faes.....8 8 9 Signature reserved.....136 Reporter's Certificate.....138 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24

Christina Pramudji, M.D.

Page 6	Page 8
<p>1 EXHIBIT INDEX</p> <p>2 PAGE</p> <p>3 Exhibit No. 1.....8</p> <p>4 Notice to Take Deposition of Christina</p> <p>5 Pramudji, M.D.</p> <p>6 Exhibit No. 2.....11</p> <p>7 Expert Report of Christina Pramudji, M.D.</p> <p>8</p> <p>9 Exhibit No. 3.....15</p> <p>10 Christina Pramudji Reliance List in</p> <p>11 Addition to Materials Referenced in</p> <p>12 Report - MDL Wave 1</p> <p>13 Exhibit No. 4.....22</p> <p>14 Curriculum Vitae</p> <p>15</p> <p>16 Exhibit No. 5.....10</p> <p>17 Placeholder</p> <p>18 Exhibit No. 6.....22</p> <p>19 Curriculum Vitae</p> <p>20</p> <p>21 Exhibit No. 7.....41</p> <p>22 Gynecare Proxima</p> <p>23 Exhibit No. 8.....56</p> <p>24 USDA UPDATE on Serious Complications</p> <p>Associated with Transvaginal Placement of</p> <p>Surgical Mesh for Pelvic Organ Prolapse:</p> <p>FDA Safety Communication</p> <p>Exhibit No. 9.....66</p> <p>FDA News Release - FDA strengthens</p> <p>requirements for surgical mesh for the</p> <p>transvaginal repair of pelvic organ</p> <p>prolapse to address safety risks</p>	<p>1 with you today that are responsive to those requests?</p> <p>2 A. Yes.</p> <p>3 Q. What are those materials that you brought</p> <p>4 today?</p> <p>5 A. Well, I brought my CV. I brought all the</p> <p>6 documents in my possession, including the thumb</p> <p>7 drives, the company educational literature, the</p> <p>8 literature in publications, all the documents that I</p> <p>9 would have used in preparation, the patient medical</p> <p>10 records, everything that I could -- that I could find,</p> <p>11 with the exception of some of the materials that were</p> <p>12 produced in prior cases and have been sent back to</p> <p>13 Butler Snow.</p> <p>14 Q. Have you brought any invoices with you today</p> <p>15 regarding your work on the Wave 1 expert reports or</p> <p>16 any of the --</p> <p>17 A. No.</p> <p>18 Q. -- case-specific reports?</p> <p>19 A. No.</p> <p>20 Q. Okay. What I'm -- have you billed for</p> <p>21 those --</p> <p>22 A. No.</p> <p>23 Q. -- those reports yet? No, you have not.</p> <p>24 When do you anticipate billing --</p>
Page 7	Page 9
<p>1 CHRISTINA PRAMUDJI, M.D.,</p> <p>2 having been first duly sworn, testified as follows:</p> <p>3 EXAMINATION</p> <p>4 QUESTIONS BY MR. FAES:</p> <p>5 Q. Dr. Pramudji, good afternoon. My name is</p> <p>6 Andy Faes. I'm here to take your deposition today</p> <p>7 regarding the Proxima device. Do you understand that?</p> <p>8 A. Yes.</p> <p>9 Q. And you understand that you're sworn to tell</p> <p>10 the truth. Correct?</p> <p>11 A. Yes.</p> <p>12 Q. Now, if I ask you -- you've been through this</p> <p>13 process before, I take it, but if I ask you a</p> <p>14 question that you don't understand, just let me know</p> <p>15 and I'll try to rephrase the question. All right?</p> <p>16 A. Sure.</p> <p>17 (Exhibit No. 1 marked.)</p> <p>18 Q. I'm going to hand you what's been marked as</p> <p>19 Exhibit No. 1 to the deposition, which is the</p> <p>20 deposition notice. Let me ask you, Dr. Pramudji, have</p> <p>21 you reviewed that document prior to today?</p> <p>22 A. Yes.</p> <p>23 Q. And attached to that notice there's a number</p> <p>24 of document requests. Have you brought any materials</p>	<p>1 A. Probably --</p> <p>2 Q. -- for those reports?</p> <p>3 A. Probably in the next few days.</p> <p>4 Q. Within the next few days?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. What I'm going to do is -- I know I'm</p> <p>7 throwing off the exhibit numbers, but I'm going to</p> <p>8 mark as Exhibit No. 5 --</p> <p>9 A. Uh-huh.</p> <p>10 Q. -- a placeholder. And if you and William</p> <p>11 could agree that when those bills become available --</p> <p>12 A. Uh-huh.</p> <p>13 Q. -- for your general reports and your</p> <p>14 case-specific reports --</p> <p>15 A. Uh-huh.</p> <p>16 Q. -- that are the subject of this notice of</p> <p>17 deposition, you'll send those to the Court Reporter</p> <p>18 and they'll substitute those out as Exhibit No. 5.</p> <p>19 A. Okay.</p> <p>20 (Exhibit No. 5 marked.)</p> <p>21 MR. GAGE: And I would say, I don't have</p> <p>22 an objection to that, except for I do know I have --</p> <p>23 Andy, I heard some generalized commentary back and</p> <p>24 forth between counsel, not you and me, that there was</p>

Christina Pramudji, M.D.

<p style="text-align: right;">Page 10</p> <p>1 some dispute -- I can't remember the details of it --</p> <p>2 some dispute as to whether or not we had gotten the</p> <p>3 invoices from Plaintiffs and their experts and we</p> <p>4 needed to have some meeting of the minds. I'm</p> <p>5 assuming we're going to ultimately get to a meeting of</p> <p>6 the minds on that. So I don't have an objection to</p> <p>7 producing them, but I do know that there is some</p> <p>8 dispute out there that we're still needing to get some</p> <p>9 from your experts. And so, you know, that's not a</p> <p>10 fight you and I need to discuss or deal with today.</p> <p>11 MR. FAES: No. I agree.</p> <p>12 (Exhibit No. 2 marked.)</p> <p>13 Q. (By Mr. Faes) Doctor, I'm going to hand you</p> <p>14 what's been marked as Exhibit No. 2.</p> <p>15 A. Uh-huh.</p> <p>16 Q. Can you tell me what that is?</p> <p>17 A. Yes. This is my expert report regarding the</p> <p>18 Gynemesh, the Prolift and the Prosima.</p> <p>19 Q. Does this report contain each of the opinions</p> <p>20 that you've reached regarding the Prosima, Prolift and</p> <p>21 Gynemesh PS?</p> <p>22 A. Yes, these are my opinions.</p> <p>23 Q. Is there any particular reason why you chose</p> <p>24 to combine your opinions on those three products into</p>	<p style="text-align: right;">Page 12</p> <p>1 the complication rates for the Prosima device are</p> <p>2 different than the Gynemesh PS flat mesh. Correct?</p> <p>3 A. Are you talking about the Gynemesh PS being</p> <p>4 used as a Prolift or just being used as a --</p> <p>5 Q. No. I'm talking about the Gynemesh just as a</p> <p>6 flat mesh.</p> <p>7 A. Oh, they're -- actually, they're pretty</p> <p>8 similar.</p> <p>9 Q. So it's your --</p> <p>10 A. I -- I'm sorry. Before I thought you were</p> <p>11 talking about the Prolift versus the Prosima, which</p> <p>12 they have slightly different rates. But with the</p> <p>13 Gynemesh and the Prosima they're pretty similar.</p> <p>14 Q. So you believe that the complication rates</p> <p>15 for the Prosima device and the Gynemesh PS flat mesh</p> <p>16 --</p> <p>17 A. Uh-huh.</p> <p>18 Q. -- are similar?</p> <p>19 A. Yes.</p> <p>20 Q. Do you agree that the Prolift device has a</p> <p>21 different safety and efficacy profile than the</p> <p>22 Gynemesh PS flat mesh?</p> <p>23 A. It has a slightly -- slightly different, but</p> <p>24 it's -- it's not a huge -- not a huge difference.</p>
<p style="text-align: right;">Page 11</p> <p>1 a single report as opposed to separating them out?</p> <p>2 A. Well, because the products are made of</p> <p>3 Gynemesh PS and a lot of the science correlates with</p> <p>4 -- with all the products, it seemed to make more sense</p> <p>5 to just combine it.</p> <p>6 Q. Would you agree that the Prosima, for</p> <p>7 example, has a different safety and efficacy profile</p> <p>8 than the Gynemesh PS flat mesh?</p> <p>9 A. It does have a different efficacy, yes. But</p> <p>10 -- but I think a lot of the general -- the general</p> <p>11 points about the different products come together</p> <p>12 nicely and the opinions can be held.</p> <p>13 Q. So you've answered my question on efficacy.</p> <p>14 A. Uh-huh.</p> <p>15 Q. Do you agree that the Prosima has a different</p> <p>16 safety profile than the Gynemesh PS flat mesh?</p> <p>17 A. It depends on what you're -- what you're</p> <p>18 talking about. There are some differences, yes.</p> <p>19 Q. You'd agree that the Prosima device has some</p> <p>20 unique risks that are unique to the Prosima. Correct?</p> <p>21 A. I don't know if they're unique risks. I'm</p> <p>22 thinking more about the rates may be different when</p> <p>23 you compare the products.</p> <p>24 Q. But as a general principle, we can agree that</p>	<p style="text-align: right;">Page 13</p> <p>1 Q. Well, you'd agree, for example, that the</p> <p>2 Prolift kit has trocars and the Gynemesh PS flat</p> <p>3 mesh and the Prosima mesh do not have trocars.</p> <p>4 Correct?</p> <p>5 A. That's correct, yes.</p> <p>6 Q. Would you agree that the trocars used in the</p> <p>7 Prolift mesh kit can introduce unique risks that are</p> <p>8 not risks of the Gynemesh PS flat mesh or the Prosima</p> <p>9 device?</p> <p>10 A. They -- they can, yes. I don't know that</p> <p>11 they're really significant looking at the literature,</p> <p>12 but that is a theory that's out there.</p> <p>13 MR. FAES: Okay. Object and move to</p> <p>14 strike after the answer "yes."</p> <p>15 Q. (By Mr. Faes) Now, in your report, which</p> <p>16 I've marked as Exhibit 2, you go through various facts</p> <p>17 and discuss facts. Did you discuss the facts that you</p> <p>18 were -- you felt were the most important in drawing</p> <p>19 your opinions in the report?</p> <p>20 A. Yes.</p> <p>21 Q. In terms of your decision making in writing</p> <p>22 the report, why did you choose to cite the articles in</p> <p>23 your report that you cited?</p> <p>24 A. Well, I try to cite as much level one</p>

4 (Pages 10 to 13)

Christina Pramudji, M.D.

Page 14	Page 16
<p>1 literature as I can, which is going to be randomized</p> <p>2 controlled trials and review studies where they're,</p> <p>3 you know, gathering together a lot of large studies</p> <p>4 because that's the highest level of literature and try</p> <p>5 to get a good sampling of the highest level studies</p> <p>6 that there are.</p> <p>7 (Exhibit No. 3 marked.)</p> <p>8 Q. Okay. I'm going to hand you what's been</p> <p>9 marked as Exhibit No. 3 to your deposition.</p> <p>10 A. Uh-huh.</p> <p>11 Q. Can you tell me what that is?</p> <p>12 A. It's the reliance list.</p> <p>13 Q. Now --</p> <p>14 MR. FAES: Do you have something to say,</p> <p>15 William, before I . .</p> <p>16 MR. GAGE: Just don't forget to -- she</p> <p>17 mentioned an updated resume. I didn't want you to</p> <p>18 forget to --</p> <p>19 MR. FAES: Oh.</p> <p>20 MR. GAGE: -- mark that as a separate</p> <p>21 exhibit, which I'm handing to you. I mean, do it</p> <p>22 after you ask the questions on the reliance list.</p> <p>23 MR. FAES: Sure.</p> <p>24 MR. GAGE: I didn't mean to interrupt</p>	<p>1 A. Butler Snow helped me to make the list.</p> <p>2 Q. Does this list contain all of the materials</p> <p>3 that you reviewed and relied upon in forming your</p> <p>4 opinions in this case?</p> <p>5 A. Yes.</p> <p>6 Q. You've mentioned that you've brought a number</p> <p>7 of materials with you.</p> <p>8 A. Uh-huh.</p> <p>9 Q. There's flash drives, there's materials</p> <p>10 stacked in front of you.</p> <p>11 A. Uh-huh.</p> <p>12 Q. Is everything -- is there anything that</p> <p>13 you brought today -- strike that. I'll start over --</p> <p>14 A. Uh-huh.</p> <p>15 Q. -- and ask a new question because you</p> <p>16 look like you're maybe a little confused.</p> <p>17 Is there anything that you brought with you</p> <p>18 today that you've reviewed and relied upon in forming</p> <p>19 your opinions on the Prolift, Prosima or Gynemesh</p> <p>20 PS --</p> <p>21 A. Uh-huh.</p> <p>22 Q. -- that is not listed on Exhibit No. 3?</p> <p>23 A. Not to my knowledge.</p> <p>24 Q. Now, you've combined your reliance</p>
Page 15	Page 17
<p>1 you.</p> <p>2 MR. FAES: Well, I already had a</p> <p>3 different one marked, so. . .</p> <p>4 MR. GAGE: Yeah. Is that -- well, he'll</p> <p>5 ask you -- he'll ask you whether you updated that one</p> <p>6 at the appropriate time. I'm sorry to interrupt. I</p> <p>7 just didn't want to forget. I handed it to you when I</p> <p>8 looked down and I saw it in my lap.</p> <p>9 MR. FAES: I don't see any difference</p> <p>10 between this and the one I have. Anyway. . .</p> <p>11 Q. (By Mr. Faes) Now, Dr. Pramudji --</p> <p>12 A. Uh-huh.</p> <p>13 Q. -- Exhibit 3 --</p> <p>14 A. Uh-huh.</p> <p>15 Q. -- is that the reliance list for both your</p> <p>16 Prosima/Gynemesh PS/Prolift report, as well as your</p> <p>17 TVT and TVTO general report?</p> <p>18 A. Yes.</p> <p>19 Q. And at this time, you haven't issued any</p> <p>20 general reports on any of the TVT products, other than</p> <p>21 the TVT retropubic device and the TVTO device. Right?</p> <p>22 A. That's correct.</p> <p>23 Q. Now, did you make this list or was it</p> <p>24 provided for you?</p>	<p>1 list for the -- we'll call them the pelvic organ</p> <p>2 prolapse products. When I say pelvic organ prolapse</p> <p>3 products, I'm referring from here on out as the</p> <p>4 Prolift, the Prosima and the Gynemesh PS. Can we</p> <p>5 agree to that?</p> <p>6 A. Yes.</p> <p>7 Q. So you combined your opinions -- strike that.</p> <p>8 You've combined your reliance list for your</p> <p>9 report on the pelvic organ prolapse products and your</p> <p>10 general report on the TVT and TVTO products. Correct?</p> <p>11 A. Yes.</p> <p>12 Q. There's one reliance list for both reports.</p> <p>13 Correct?</p> <p>14 A. Yes.</p> <p>15 Q. In forming your opinions, did you rely on</p> <p>16 midurethral slings -- strike that.</p> <p>17 In forming your opinions on the POP products,</p> <p>18 did you rely on midurethral strings [sic] and the TVT</p> <p>19 to form any of your opinions regarding the safety and</p> <p>20 efficacy of the Prolift?</p> <p>21 MR. GAGE: Object to form.</p> <p>22 A. Not for the -- not for the major substance of</p> <p>23 my opinions. I mean, for, you know, peripheral</p> <p>24 knowledge, I think it helps support the safety of the</p>

5 (Pages 14 to 17)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 18</p> <p>1 mesh, but obviously they're very different products, 2 so you can't draw too many conclusions -- 3 Q. (By Mr. Faes) Okay. So same -- 4 A. -- on the general safety of the mesh. 5 Q. Sorry. I didn't mean to interrupt you. So 6 same question: Prosima and Gynemesh PS, in forming 7 your opinions, did you rely on midurethral slings and 8 the TVT to form any of your opinions regarding the 9 safety and efficacy of the Gynemesh PS or the Prosima? 10 A. I'm sorry. Wasn't that the same question 11 that I just answered? 12 Q. You answered it for Prolift the first time. 13 A. Oh, okay. Well, it would be the same answer. 14 Q. Okay. Thank you. Now, when were you first 15 contacted about being a general expert in this case 16 regarding the Prosima? 17 A. Well, the M -- this M -- this big MDL wave 18 was in November. 19 Q. Okay. 20 A. But there was another Prosima case prior to 21 that, maybe a year, year and a half ago. 22 Q. Right. You're referring to the Caviness 23 case -- 24 A. Right.</p>	<p style="text-align: right;">Page 20</p> <p>1 because it was Texas -- 2 MR. FAES: Right. And you guys -- 3 THE WITNESS: -- Federal court. 4 MR. FAES: And you guys never do any 5 more than that. 6 THE REPORTER: We have to do this one at 7 a time, please. 8 MR. FAES: Sorry. 9 MR. FAES: Okay. So I'll just ask if 10 the -- that -- if one was created for the Caviness 11 case, a written report, that you provide that to us. 12 Q. (By Mr. Faes) How many hours would you 13 -- strike that. I'm going to ask a different 14 question. 15 When were you first contacted about being an 16 expert in this case regarding the Gynemesh PS? 17 A. When you say "this case," you mean -- what do 18 you mean specifically? 19 Q. I mean this Wave 1 general expert report. 20 A. This. Oh, okay. So that all just started in 21 November. 22 Q. Have you -- do you have an estimate of the 23 number of hours that you've spent preparing this 24 report which is marked as Exhibit 3?</p>
<p style="text-align: right;">Page 19</p> <p>1 Q. -- where you were asked by Butler Snow to be 2 an expert? 3 A. Yes. 4 Q. But you didn't prepare a written report 5 in that case. Correct? 6 A. I honestly can't recall. I don't know. I 7 can't remember. At this point, I'd have to look back 8 at my records. 9 MR. FAES: Okay. And I'd ask if one was 10 -- was created that it be produced to us, but, 11 William, correct me if I'm wrong, I'm pretty sure 12 there wasn't. It was just an expert disclosure. 13 Right? 14 MR. GAGE: Andy -- 15 THE WITNESS: I think -- 16 MR. GAGE: -- I honestly don't know, but 17 I will tell you, my sense is -- 18 THE WITNESS: That's right. 19 MR. GAGE: -- in Texas State court, I 20 think the rule is we only had to do disclosures and 21 not reports. 22 MR. FAES: Yeah. 23 MR. GAGE: And I think you're -- 24 THE WITNESS: Yeah, that's what it --</p>	<p style="text-align: right;">Page 21</p> <p>1 A. Yeah. Probably, I would say -- I would 2 estimate about 50 hours. 3 Q. Now, that 50 hours, is that for the entire 4 report for all three of the pelvic organ prolapse 5 products? 6 A. Yes. 7 Q. How many hours of that 50 would you say you 8 spent actually drafting the report? 9 A. Probably about 20. 10 Q. And how many of those hours would you say you 11 spent reviewing materials that went into the report? 12 A. About 30. A lot of the materials I was 13 already familiar with from previous cases. 14 (Exhibit No. 4 marked.) 15 Q. Okay. I'm going to hand you what's been 16 marked as Exhibit 4, which is the -- your CV that was 17 produced to us. And I'm also going to mark as 18 Exhibit 6 the CV that counsel just gave me, which was 19 represented as your updated CV. At first glance, I 20 couldn't tell my difference to it. We'll refer to 21 Exhibit 6 most of the time. 22 (Exhibit No. 6 marked.) 23 Q. So if you look at Exhibit No. 6, which has 24 been represented as your current updated CV, there's a</p>

6 (Pages 18 to 21)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 22</p> <p>1 list of publications. Correct?</p> <p>2 A. Correct.</p> <p>3 Q. Do any of the publications listed in your CV</p> <p>4 specifically address the Prosima product?</p> <p>5 A. No.</p> <p>6 Q. Do any of the publications listed in your</p> <p>7 report specifically address the Gynemesh PS products?</p> <p>8 A. No.</p> <p>9 Q. Do any of the publications in your report</p> <p>10 specifically address the transvaginal technique for</p> <p>11 the treatment of prolapse?</p> <p>12 MR. GAGE: Object to form. Your -- the</p> <p>13 -- and I'll object to the form to last two -- the last</p> <p>14 two questions. You've asked the question: Do any of</p> <p>15 the publications listed in your report. I'm thinking</p> <p>16 you're meaning to say listed in your CV.</p> <p>17 MR. FAES: I do mean that, so I'll --</p> <p>18 thank you, William. I'll re-ask the question.</p> <p>19 MR. GAGE: Yeah.</p> <p>20 Q. (By Mr. Faes) Do any of the --</p> <p>21 MR. GAGE: Well, she was giving an</p> <p>22 incorrect answer by saying no and so I felt it was</p> <p>23 important to. . .</p> <p>24 THE WITNESS: Oh, I knew what -- I knew</p>	<p style="text-align: right;">Page 24</p> <p>1 Q. You've never treated -- strike that.</p> <p>2 You've never published any peer-reviewed</p> <p>3 literature in the area of treating mesh complications</p> <p>4 either. Is that correct?</p> <p>5 A. That's correct.</p> <p>6 Q. Now, you've used the Prosima in your</p> <p>7 practice. Correct?</p> <p>8 A. Yes, I have.</p> <p>9 Q. And you've implanted about 75 of them. Is</p> <p>10 that --</p> <p>11 A. That's sounds about right, yes.</p> <p>12 Q. Can you tell me when you first implanted the</p> <p>13 Prosima device?</p> <p>14 A. Let's see. It was shortly after it came out,</p> <p>15 which I believe was in 2008, if I remember correctly.</p> <p>16 So that would have been -- you know -- shortly after</p> <p>17 it was launched I -- was when when I tried it.</p> <p>18 Q. Now, you wrote in your report, I believe,</p> <p>19 that the Prosima didn't have a full launch until -- I</p> <p>20 can't find it. I believe you wrote in your expert</p> <p>21 report that the Prosima device didn't have a full</p> <p>22 launch until later in -- later in 2010. Is that</p> <p>23 correct?</p> <p>24 A. (No response.)</p>
<p style="text-align: right;">Page 23</p> <p>1 what he meant.</p> <p>2 MR. FAES: That's the one time when I</p> <p>3 appreciate the speaking objection, William.</p> <p>4 MR. GAGE: Yes.</p> <p>5 Q. (By Mr. Faes) Do any of the -- Dr. Pramudji,</p> <p>6 do any of the publications listed in your curriculum</p> <p>7 vitae specifically address the Gynemesh PS product?</p> <p>8 A. No.</p> <p>9 Q. Do any of the publications listed in your</p> <p>10 curriculum vitae specifically address the transvaginal</p> <p>11 technique for the treatment of pelvic organ prolapse?</p> <p>12 A. No.</p> <p>13 Q. Would you agree that the Prosima is an</p> <p>14 alternative surgical treatment -- strike that.</p> <p>15 Would you agree that the Prosima is an</p> <p>16 alternative surgical procedure for the treatment of</p> <p>17 prolapse as compared to other techniques that are</p> <p>18 available to physicians?</p> <p>19 MR. GAGE: Object to form.</p> <p>20 A. Yes.</p> <p>21 Q. (By Mr. Faes) You've never published any</p> <p>22 peer-reviewed literature in the area of mesh</p> <p>23 complications. Correct?</p> <p>24 A. That's correct.</p>	<p style="text-align: right;">Page 25</p> <p>1 Q. It's Page 41 that you said it was not widely</p> <p>2 launched until August of 2010.</p> <p>3 MR. GAGE: Object to form.</p> <p>4 Q. (By Mr. Faes) Broadly launched. And it's</p> <p>5 top of Page 40. My mistake.</p> <p>6 MR. GAGE: Object to form.</p> <p>7 A. Oh, yes, that's correct. I got the dates</p> <p>8 confused. So it would have been after that.</p> <p>9 Q. (By Mr. Faes) So that -- what you said</p> <p>10 earlier was incorrect, you don't believe --</p> <p>11 A. Yeah.</p> <p>12 Q. -- that you first implanted it in 2008?</p> <p>13 A. That's -- yeah, that's incorrect. I got the</p> <p>14 dates confused, yeah.</p> <p>15 Q. So you believe that you -- and actually, I</p> <p>16 was going to ask you later about that date on Page 40</p> <p>17 of your report.</p> <p>18 A. Uh-huh.</p> <p>19 Q. Are you sure that's correct, that it was --</p> <p>20 wasn't widely launched until August of 2010?</p> <p>21 MR. GAGE: Object to form.</p> <p>22 Q. (By Mr. Faes) Do you think it might have</p> <p>23 been August of 2009?</p> <p>24 A. I would have to -- I'd have to look back at</p>

7 (Pages 22 to 25)

Christina Pramudji, M.D.

Page 26	Page 28
<p>1 my references.</p> <p>2 Q. Okay. But, at any rate, you believe you</p> <p>3 didn't begin using the Prosima device until it was</p> <p>4 officially launched in either 2009 or 2010, whatever</p> <p>5 the date may be, by Ethicon. Correct?</p> <p>6 A. That's correct, yes.</p> <p>7 Q. But you know that it -- that the Prosima</p> <p>8 device was actually cleared in 2007?</p> <p>9 A. Yes.</p> <p>10 Q. And was available to a limited number</p> <p>11 of physicians who were conducting trials and studies</p> <p>12 on the device. Is that correct?</p> <p>13 A. Yes.</p> <p>14 Q. So you -- you were not, as far as you know,</p> <p>15 one of the people that was involved in conducting a</p> <p>16 clinical trial on the Prosima or using the Prosima</p> <p>17 prior to its full launch by Ethicon. Is that right?</p> <p>18 A. That's correct.</p> <p>19 Q. Now, you use Gynemesh PS in your medical</p> <p>20 practice, as well. Is that correct?</p> <p>21 A. I have used it in the past on a few</p> <p>22 occasions.</p> <p>23 Q. How many times would you estimate you've used</p> <p>24 the Gynemesh PS?</p>	<p>1 A. Absolutely.</p> <p>2 Q. What mesh -- meshes do you use if you need a</p> <p>3 flat mesh, for example?</p> <p>4 A. Well, I -- I haven't really used just a flat</p> <p>5 mesh. I've used -- I've used -- I use the Elevate.</p> <p>6 Q. Still?</p> <p>7 A. No.</p> <p>8 Q. When did you stop using the Elevate?</p> <p>9 A. Well, they've -- they've now stopped</p> <p>10 producing it, so. . .</p> <p>11 Q. When did they stop producing it?</p> <p>12 A. I think -- I think they're in the process of</p> <p>13 stopping, but they announced a couple of weeks ago</p> <p>14 that they are not going to produce it anymore.</p> <p>15 Q. How did you learn of that announce many?</p> <p>16 A. Through an e-mail from ASTORA.</p> <p>17 Q. From -- was it from your sales rep or. . .</p> <p>18 A. No. It was from corporate.</p> <p>19 Q. Okay. And did they say when in that e-mail</p> <p>20 that they would officially stop --</p> <p>21 A. Yes --</p> <p>22 Q. -- making it available for sale?</p> <p>23 A. -- but I can't remember the date. I think if</p> <p>24 the hospitals still have it, it could be used, but,</p>
Page 27	Page 29
<p>1 A. The free cut Gynemesh PS, is that what you're</p> <p>2 referring to.</p> <p>3 Q. Yes. Yes, the flat -- the Gynemesh PS, the</p> <p>4 flat mesh.</p> <p>5 A. Maybe a dozen times.</p> <p>6 Q. Do you recall during what time period you've</p> <p>7 used the Gynemesh PS?</p> <p>8 A. Going back to 2002 and then going forward to</p> <p>9 probably 2011.</p> <p>10 Q. So when you used the Gynemesh prior to 2005,</p> <p>11 did you just use it where you would cut portions of it</p> <p>12 to help you in treating prolapse when you were doing</p> <p>13 native tissue repair?</p> <p>14 A. That's correct.</p> <p>15 Q. Okay. And why did you stop using it in 2011?</p> <p>16 A. Because of the environment around that</p> <p>17 transvaginal mesh with the patients being more wary of</p> <p>18 it and feeling reluctant to have mesh implants.</p> <p>19 Q. So you would agree that you moved away from</p> <p>20 using mesh for pelvic organ prolapse repair?</p> <p>21 A. Yes. Not completely, but, yes. The</p> <p>22 environment was not conducive to using it.</p> <p>23 Q. So when you -- do you still use mesh</p> <p>24 occasionally for pelvic organ prolapse repair?</p>	<p>1 you know, I think patients might feel uncomfortable</p> <p>2 with that. So next time that I need a transvaginal</p> <p>3 mesh, I'll probably use the Boston Scientific mesh.</p> <p>4 Q. Which Boston Scientific mesh do you believe</p> <p>5 you'd use?</p> <p>6 A. Well, I think they only have one transvaginal</p> <p>7 kit right now and I can't recall the name of it.</p> <p>8 Q. Is it the Uphold product?</p> <p>9 A. Uphold, yes.</p> <p>10 Q. I got a little sidetracked with the Elevate</p> <p>11 stuff.</p> <p>12 A. Okay.</p> <p>13 Q. So if you need a -- if you needed a -- strike</p> <p>14 that.</p> <p>15 When is the last time that you recall using a</p> <p>16 flat mesh that you cut yourself or inserted in whole</p> <p>17 in a pelvic organ prolapse repair?</p> <p>18 A. So not a kit --</p> <p>19 Q. Right.</p> <p>20 A. -- you mean?</p> <p>21 Q. Right. A flat mesh like the Gynemesh PS.</p> <p>22 A. The last time would probably be in 2011,</p> <p>23 because at that point I only used it to supplement a</p> <p>24 to Total Prolift that had a large apical defect. So,</p>

8 (Pages 26 to 29)

Christina Pramudji, M.D.

Page 30	Page 32
<p>1 at that point, I wasn't even using it by itself. I</p> <p>2 used it in conjunction with the Prolift. I would</p> <p>3 fashion a greater apical support with the free mesh,</p> <p>4 if that makes sense. So where the Total Prolift would</p> <p>5 go across the apex, I would supplement with the</p> <p>6 Gynemesh. So the last time that I would have used a</p> <p>7 free cut mesh just to supplement was probably</p> <p>8 pre-Prolift.</p> <p>9 Q. Okay. If you -- let me ask you this: If you</p> <p>10 had a patient with a large defect that you didn't feel</p> <p>11 you could repair using either native tissue or suture</p> <p>12 repair or a biologic mesh, would you consider using a</p> <p>13 synthetic mesh?</p> <p>14 A. Yes.</p> <p>15 Q. What synthetic -- what would be your</p> <p>16 synthetic mesh of choice in that situation?</p> <p>17 A. I don't know. I don't know who -- I don't</p> <p>18 even know if they still make Gynemesh, because I</p> <p>19 haven't used it in so long. I don't even know if that</p> <p>20 product --</p> <p>21 Q. So --</p> <p>22 A. If that product is available, I would use</p> <p>23 Gynemesh.</p> <p>24 Q. So, sitting here today, you don't know</p>	<p>1 Q. Yes.</p> <p>2 A. No, I don't know.</p> <p>3 Q. Do you know what sizes and configurations the</p> <p>4 Gynemesh PS currently is available in?</p> <p>5 A. No.</p> <p>6 Q. You stated earlier that you stopped using the</p> <p>7 Gynemesh PS, I think, because of the environment?</p> <p>8 A. Yes.</p> <p>9 Q. Did you say -- did I get that right?</p> <p>10 A. That's correct.</p> <p>11 Q. What do you mean by that?</p> <p>12 A. Well, when there's, you know, wall-to-wall</p> <p>13 litigation commercials, patients look askew at mesh</p> <p>14 procedures. And so they -- they get scared and they</p> <p>15 want to look at other alternatives.</p> <p>16 Q. When did you first begin to use a mesh kit</p> <p>17 for the treatment of prolapse?</p> <p>18 A. 2005.</p> <p>19 Q. And what was the first kit that you used?</p> <p>20 A. The Prolift.</p> <p>21 Q. And other than that kit, is the only other</p> <p>22 kit you've used on a -- not counting, like, cadaver</p> <p>23 labs --</p> <p>24 A. Uh-huh.</p>
Page 31	Page 33
<p>1 whether or not the Gynemesh PS is still available or</p> <p>2 not?</p> <p>3 A. I do not know.</p> <p>4 Q. Have you ever used the Prolene Soft product?</p> <p>5 A. I always get the different nomenclatures</p> <p>6 confused. Is that the same one as Prolift Plus M?</p> <p>7 Q. No, it is not.</p> <p>8 A. Okay. Is that the Vypro?</p> <p>9 Q. No.</p> <p>10 A. Okay. What is the --</p> <p>11 Q. So -- so let me ask you this: Sitting here</p> <p>12 today, do you know what the Prolene Soft mesh is?</p> <p>13 A. No, I don't.</p> <p>14 Q. Do you know if there is any difference</p> <p>15 between the Prolene Soft mesh and the Gynemesh PS</p> <p>16 mesh?</p> <p>17 A. I can't recall right now.</p> <p>18 Q. So if they're identical, you wouldn't know</p> <p>19 that one way or the other?</p> <p>20 A. I can't recall what Prolene Soft is.</p> <p>21 Q. Okay. So it's probably also fair to say that</p> <p>22 you don't know if there's a price difference between</p> <p>23 the Gynemesh PS or the Prolene Soft mesh?</p> <p>24 A. A price difference?</p>	<p>1 Q. -- but in a -- on a live human woman, is the</p> <p>2 only other kit that you've used the Elevate?</p> <p>3 A. Elevate, the Prosima --</p> <p>4 Q. Oh, yeah, the Prosima and the --</p> <p>5 A. -- and the Uphold.</p> <p>6 Q. You have used the Uphold?</p> <p>7 A. Yes.</p> <p>8 Q. When did you first use that?</p> <p>9 A. I don't recall. It was several years ago.</p> <p>10 Q. And has it -- when's the last time that you</p> <p>11 used the Uphold kit?</p> <p>12 A. I really have only tried it a couple of times</p> <p>13 and that was a few years ago.</p> <p>14 Q. Okay. And you've also used -- I think you</p> <p>15 just forgot to mention it -- you've used the Prolift</p> <p>16 Plus M --</p> <p>17 A. Yes.</p> <p>18 Q. -- kit before, as well.</p> <p>19 A. Yes.</p> <p>20 Q. Correct?</p> <p>21 A. Uh-huh, that's correct.</p> <p>22 MR. GAGE: Let me just remind you --</p> <p>23 THE WITNESS: Yes.</p> <p>24 MR. GAGE: -- the way the Court Reporter</p>

Christina Pramudji, M.D.

Page 34	Page 36
<p>1 has to work, Andy -- let Andy really completely fully</p> <p>2 finish his question --</p> <p>3 THE WITNESS: Uh-huh.</p> <p>4 MR. GAGE: -- before you answer, because</p> <p>5 I'm reading the transcript here and a lot of times</p> <p>6 you're answering before Andy is finished. And we want</p> <p>7 to make it nice and clean for the record, so I may</p> <p>8 from time to time nudge you on that point.</p> <p>9 MR. FAES: And the Court Reporter</p> <p>10 appreciates it, too.</p> <p>11 MR. GAGE: Yeah.</p> <p>12 Q. (By Mr. Faes) Now, during the time that you</p> <p>13 were using the Prosima, did you also continue to do</p> <p>14 native tissue repairs with sutures?</p> <p>15 A. Yes, I did.</p> <p>16 Q. Did you view the native tissue repairs with</p> <p>17 sutures as an alternative to the Prosima and vice</p> <p>18 versa?</p> <p>19 A. Yes.</p> <p>20 Q. And you've also done abdominal</p> <p>21 sacrocolpopexy. Correct? I tried to say that</p> <p>22 correct. I don't know if I did or not.</p> <p>23 A. That was close. Yes. I really started doing</p> <p>24 that primarily, though, after 2011 when the</p>	<p>1 A. Y mesh. They're all Y meshes.</p> <p>2 Q. But you don't use the Ethicon Artisyn mesh?</p> <p>3 MR. GAGE: Object. Form.</p> <p>4 A. I tried it a couple times, but I didn't -- I</p> <p>5 didn't prefer it. It was harder to work with in</p> <p>6 surgery than the Restorelle in my hands.</p> <p>7 Q. (By Mr. Faes) So it would be fair to say</p> <p>8 that currently when you do abdominal sacrocolpopexy</p> <p>9 procedure, your mesh of choice is the Coloplast</p> <p>10 Restorelle?</p> <p>11 A. That's correct.</p> <p>12 Q. When you consent a patient for a mesh kit,</p> <p>13 such as the Prosima device, do you -- did you talk to</p> <p>14 them about the specific manufacturer and compared the</p> <p>15 kits with them that were available to use or did you</p> <p>16 just talk about vaginal mesh, in general, and then you</p> <p>17 chose the kit for that patient?</p> <p>18 MR. GAGE: Object to form.</p> <p>19 A. I would talk about the vaginal mesh in</p> <p>20 general and maybe with the Prosima some of the nuances</p> <p>21 compared to the Prolift, but I -- other than that, I</p> <p>22 didn't compare it to different kits. I don't think</p> <p>23 patients would really be able to -- most patients</p> <p>24 would not be able to fully understand or appreciate</p>
Page 35	Page 37
<p>1 transvaginal mesh became controversial.</p> <p>2 Q. When did you first start to perform that</p> <p>3 procedure?</p> <p>4 A. I did a handful prior to 2011, but I really</p> <p>5 started using it more after 2011.</p> <p>6 Q. In terms of an alternative treatment for a</p> <p>7 patient, would you agree that abdominal sacrocolpopexy</p> <p>8 would be one of the alternatives if, in fact, there</p> <p>9 were prolapse in the part of a -- in the part of a</p> <p>10 pelvis that would be appropriate for that treatment?</p> <p>11 MR. GAGE: Object. Form.</p> <p>12 A. I don't understand the last part of your</p> <p>13 question.</p> <p>14 Q. (By Mr. Faes) You know what, I'll strike</p> <p>15 that and ask a new one.</p> <p>16 What meshes have you used for abdominal sacro</p> <p>17 -- I'll just say ASC. Okay? What meshes have you</p> <p>18 used for AFC -- ASC?</p> <p>19 A. I've used the Ethicon product.</p> <p>20 Q. Okay.</p> <p>21 A. The Coloplast product, which is called</p> <p>22 Restorelle, R-E-S-T-O-R-E-L-L-E. And that's what I</p> <p>23 use currently. And I've also used the AMS product.</p> <p>24 Q. The Y mesh or. . .</p>	<p>1 the differences between the different kits.</p> <p>2 Q. (By Mr. Faes) Okay. So that kind of brings</p> <p>3 --</p> <p>4 A. I didn't see much -- I didn't much use for</p> <p>5 that.</p> <p>6 Q. Okay. So that kind of brings me to my next</p> <p>7 question: You -- what's the time period that you</p> <p>8 performed the Prolift device? From 2005 until it</p> <p>9 was no longer available in 2012?</p> <p>10 A. Yes, that's correct.</p> <p>11 Q. And you were performing the Prosima from</p> <p>12 either 2009 or 2010, whenever the launch date was,</p> <p>13 until its discontinuance. Right?</p> <p>14 A. That's correct.</p> <p>15 Q. So during the time when you were implanting</p> <p>16 both Prosima devices and Prolift devices, how did you</p> <p>17 decide which kit to use for which patient?</p> <p>18 A. The Prosima is best suited for a grade 2 or 3</p> <p>19 cystocele or rectocele without loss of apical support.</p> <p>20 If they needed more apical support or they had other</p> <p>21 factors that I thought they needed more support, then</p> <p>22 I would do the Prolift.</p> <p>23 Q. So is it fair to say that the Prosima was</p> <p>24 your device of choice for a patient that had a grade 2</p>

10 (Pages 34 to 37)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 38</p> <p>1 or 3 rectocele or cystocele without loss of apical 2 support? 3 A. Yes. 4 Q. And your -- was your Prolift your device of 5 choice for all other patients or was there a specific 6 subset of patients that that was your device of choice 7 for? 8 A. That was definitely my device of choice for 9 the more severe prolapse patients, grade 4s or some 10 grade 3s, as well, just depending on -- all grade 3s 11 are not the same. They can have different angles and 12 different areas that need support and some of those 13 would get a Prolift, as well. 14 Q. Now, like the Prosima device, the Elevate 15 does not have trocar passes. Is that correct? 16 A. That's correct. 17 Q. One significant difference between -- strike 18 that. 19 The fact that there were no external trocar 20 passes with the Elevate or the Prosima, did you see 21 that as a potential benefit from a safety perspective 22 as compared to the Prolift? 23 A. Yes, I did. You -- you do avoid some 24 bleeding that could occur with a trocar pass. I</p>	<p style="text-align: right;">Page 40</p> <p>1 can look at it. 2 (Break.) 3 Q. (By Mr. Faes) Dr. Pramudji, we're back on 4 the record after a short break. Are you ready to 5 proceed? 6 A. Yes. 7 (Exhibit No. 7 marked.) 8 Q. Before I -- before the break, I had asked you 9 whether or not the Prosima IFU states that the device 10 is indicated for grade 2 or 3 rectocele or cystocele 11 and I handed you what's been marked as Exhibit No. 7 12 to your deposition, which is the 2010 Prosima IFU. 13 Are you -- have you reviewed that document and are you 14 prepared to answer the question? 15 A. Yes. I do not see in there where it says 16 that it's indicated for that. 17 Q. Had she -- 18 MR. GAGE: Hang on just a second. Okay. 19 Go ahead. 20 Q. (By Mr. Faes) But you did mention that you 21 believe that it was -- that information was contained 22 in professional education materials? 23 A. Yes. 24 Q. Let me ask you this: Do you know if Ethicon</p>
<p style="text-align: right;">Page 39</p> <p>1 didn't have any other complications with the trocar 2 passes than bleeding at times, but for that reason it 3 would have a slightly -- a slight advantage to the 4 Prosima. 5 Q. Now, you talked a little bit about -- a 6 minute ago about the Prosima device being best for 7 grade 2 or 3 defects. Is that correct? 8 A. Yes. 9 Q. Is there anything, as you sit here today, 10 that you know of in the IFU that tells physicians that 11 the device is best for those two grades of prolapse? 12 A. I believe it does state that in the IFU and I 13 know that that is what we taught in the prof ed, as 14 well. 15 Q. So you believe it states in the Prolift IFU 16 that it is only indicated for grade 2 or 3 defects? 17 MR. GAGE: Object. Form. 18 A. I know it's in some of the literature that 19 the company put out. I'd have to look and see if it's 20 in the IFU that I'm picturing in my head right now. 21 Can I look at it? 22 Q. (By Mr. Faes) Yeah. 23 MR. FAES: Do you want to go off the 24 record for just a second? I need some water and she</p>	<p style="text-align: right;">Page 41</p> <p>1 keeps track of who those professional materials go to? 2 A. I have no idea. 3 Q. You would agree that the IFU, which is 4 Exhibit No. 7 in front of you, is required by law to 5 be in every Prosima product that is sold to 6 physicians. Is that correct? 7 A. Correct. 8 Q. So we can ensure -- strike that. 9 By contrast, the professional education 10 materials provided by Ethicon are not in every box of 11 the product that goes out to physicians. Is that 12 correct? 13 A. Of course not. 14 Q. Doctor, do you know the clearance date for 15 the Gynemesh PS flat mesh product? 16 A. I think it goes back to 2002. 17 Q. And do you know when the Gynemesh PS product 18 was first launched in the United States? 19 A. No, I don't. 20 Q. And I'll take it, since you don't know what 21 the Prolene Soft product is, you don't know what the 22 clearance date is for that product either? 23 A. Correct. 24 Q. And you don't know when the Prolene Soft</p>

11 (Pages 38 to 41)

Christina Pramudji, M.D.

Page 42	Page 44
<p>1 product was first available for use by physicians in</p> <p>2 the United States?</p> <p>3 A. That's right.</p> <p>4 Q. Do you know the clearance date for the</p> <p>5 Prosima product? I think we talked about this a</p> <p>6 little earlier.</p> <p>7 A. I think it was around 2008.</p> <p>8 Q. But you don't know any more specific than</p> <p>9 that --</p> <p>10 A. No.</p> <p>11 Q. -- sitting here today? Do you recall if you</p> <p>12 -- if you listed that clearance date for either the</p> <p>13 Gynemesh PS or the Prosima product in your report?</p> <p>14 A. I think I did. I can -- I'd have to look and</p> <p>15 see exactly where I put it in here.</p> <p>16 Q. Okay. I don't -- I don't want to take the</p> <p>17 time right now, but we'll just -- we'll just have your</p> <p>18 answer stand that you believe it's in there.</p> <p>19 Let me ask you this, Doctor: Would you --</p> <p>20 have you ever used a medical device for something that</p> <p>21 it was not indicated for?</p> <p>22 A. No.</p> <p>23 Q. Is that something you would consider doing,</p> <p>24 is using a medical device for something off label or</p>	<p>1 transvaginal use?</p> <p>2 A. Yes, it is.</p> <p>3 Q. So you believe, as you sit here today, that</p> <p>4 the Gynemesh PS mesh is indicated for transvaginal</p> <p>5 use?</p> <p>6 A. Yes.</p> <p>7 Q. Do you recall sitting -- as you sit here</p> <p>8 today, if you've reviewed the 2013 Gynemesh PS flat</p> <p>9 mesh IFU?</p> <p>10 A. I'm sure I have, but I'd have to refresh my</p> <p>11 memory on that.</p> <p>12 Q. Okay. Do you recall, as you sit here today,</p> <p>13 if you've reviewed the 2015 Gynemesh flat mesh IFU</p> <p>14 that's available on Ethicon's website?</p> <p>15 A. I'm sure I have, but I'd have to review</p> <p>16 specifics.</p> <p>17 Q. Do you agree with the FDA's viewpoint that</p> <p>18 there is a need for more rigorous studies regarding</p> <p>19 the safety and efficacy of mesh kits?</p> <p>20 MR. GAGE: Object to form.</p> <p>21 A. No, I disagree with them, because I think</p> <p>22 that we have a very strong body of data showing that</p> <p>23 the mesh kits are safe and effective.</p> <p>24 Q. (By Mr. Faes) Have you ever seen the 522</p>
Page 43	Page 45
<p>1 something that was not specifically in its indications</p> <p>2 for use?</p> <p>3 A. Absolutely. As a trained surgeon, I use my</p> <p>4 professional judgment and sometimes there are</p> <p>5 situations where you use things off label, medications</p> <p>6 or potentially, devices. I haven't used a device off</p> <p>7 label that I can recall. I have used a medication off</p> <p>8 label and discussed that with the patient, but that's</p> <p>9 within the prerogative of the physician to use their</p> <p>10 judgment.</p> <p>11 Q. And I take it -- you understand that surgical</p> <p>12 mesh is a medical device. Correct?</p> <p>13 A. Yes.</p> <p>14 Q. So you've never used a surgical mesh off</p> <p>15 label in your -- how many years have you been</p> <p>16 practicing?</p> <p>17 A. Fifteen years.</p> <p>18 Q. You've never used a -- so I'll restart the</p> <p>19 question: You've never used a surgical mesh off label</p> <p>20 in your 15 years of practice that you can recall.</p> <p>21 Correct?</p> <p>22 A. That's correct.</p> <p>23 Q. Do you know, sitting here today, whether or</p> <p>24 not the Gynemesh PS flat mesh is indicated for</p>	<p>1 order that was issued by the FDA with regard to the</p> <p>2 Prosima?</p> <p>3 A. I'm sure that I have at some point.</p> <p>4 Q. Do you recall, sitting here today, what it</p> <p>5 said?</p> <p>6 A. I can't recall.</p> <p>7 Q. Have you seen Ethicon's response to the 522</p> <p>8 order on the Prosima?</p> <p>9 A. I'm sure that I have, but I couldn't -- I</p> <p>10 couldn't recite it to you.</p> <p>11 Q. Do you recall, as you sit here today, if in</p> <p>12 response to Ethicon's -- strike that.</p> <p>13 Do you recall, as you sit here today, if in</p> <p>14 response to the FDA's 522 on the Prosima, Ethicon</p> <p>15 tried to get the FDA to accept studies that it had</p> <p>16 already done on the Prosima in lieu of a 522 study?</p> <p>17 MR. GAGE: Object to form.</p> <p>18 A. I'm not sure if I know about that or not. I</p> <p>19 don't recall.</p> <p>20 Q. (By Mr. Faes) Has anyone ever told you why</p> <p>21 the Prosima was removed from the market?</p> <p>22 MR. GAGE: Object to form.</p> <p>23 A. Not that I recall.</p> <p>24 Q. (By Mr. Faes) Do you have an understanding,</p>

12 (Pages 42 to 45)

Christina Pramudji, M.D.

Page 46	Page 48
<p>1 as you sit here today, of why the Prosima was removed</p> <p>2 from the market?</p> <p>3 MR. GAGE: Object to form.</p> <p>4 A. My understanding is that it was a calculation</p> <p>5 of being able to sell the product and having the</p> <p>6 resources to do the research that was required for the</p> <p>7 522. That was my understanding. I can't recall who</p> <p>8 told me that.</p> <p>9 Q. (By Mr. Faes) Let me ask you this: Do you</p> <p>10 intend to offer any opinions in this case about why</p> <p>11 the Prosima was removed from the market?</p> <p>12 MR. GAGE: Object to form.</p> <p>13 A. I am not sure.</p> <p>14 Q. (By Mr. Faes) Would you agree that from the</p> <p>15 time that the Ethicon did a full launch of the Prosima</p> <p>16 product until the time they stopped making it and it</p> <p>17 was no longer available, it was less than three years?</p> <p>18 A. That's correct.</p> <p>19 Q. Do you know how many Prosima devices Ethicon</p> <p>20 sold during that time?</p> <p>21 A. No, I don't.</p> <p>22 Q. Do you recall specifically how you found</p> <p>23 out that the Prosima device was no longer going to</p> <p>24 be available for sale?</p>	<p>1 stopped selling the product?</p> <p>2 A. Yes, they did.</p> <p>3 Q. Do you know what they did with those</p> <p>4 products?</p> <p>5 A. They kept them so that I could use them.</p> <p>6 Q. So you used -- continued to use the Prosima</p> <p>7 device after the announcement was made that it was no</p> <p>8 longer going to be available?</p> <p>9 A. Yes.</p> <p>10 Q. How many Prosima devices did you use --</p> <p>11 A. I don't recall.</p> <p>12 Q. -- during that time period?</p> <p>13 A. I don't know.</p> <p>14 Q. Do you recall when the last Prosima device</p> <p>15 you placed was?</p> <p>16 A. No, I don't remember.</p> <p>17 Q. Do you know what the shelf life of the</p> <p>18 Prosima product is?</p> <p>19 A. No.</p> <p>20 Q. Is it your usual practice to check the</p> <p>21 expiration date before you implant the product --</p> <p>22 A. Absolutely.</p> <p>23 Q. -- in a person?</p> <p>24 A. Sorry. Sorry to interrupt. Yes, absolutely.</p>
Page 47	Page 49
<p>1 A. No, I don't recall.</p> <p>2 Q. Do you recall the month or the year when that</p> <p>3 occurred?</p> <p>4 A. No.</p> <p>5 Q. Do you recall if you had, like, a warning</p> <p>6 period -- was -- strike that.</p> <p>7 Was there a time between when you were</p> <p>8 told that the Prosima was going to be -- was no</p> <p>9 longer going to be available for sale and when it</p> <p>10 was actually not available for sale?</p> <p>11 A. Yes.</p> <p>12 Q. Do you recall what hospitals you worked at</p> <p>13 during that time period when -- between when Prosima</p> <p>14 -- the announcement on Prosima was first made that it</p> <p>15 was no longer going to be sold and when it was</p> <p>16 ultimately no longer available?</p> <p>17 A. Yes.</p> <p>18 Q. Which hospitals were those?</p> <p>19 A. Memorial Hermann, Memorial City.</p> <p>20 Q. Okay.</p> <p>21 A. And Memorial Hermann Katy and St. Catherine's</p> <p>22 Hospital.</p> <p>23 Q. Do you know if any of those hospitals still</p> <p>24 had Prosima devices on their shelves after Ethicon</p>	<p>1 Q. And to your knowledge, you've never implanted</p> <p>2 a product that was past the expiration date. Is that</p> <p>3 correct?</p> <p>4 A. Not to my knowledge.</p> <p>5 Q. Did you ask the hospital to buy up or</p> <p>6 stockpile any Prosima devices before it was no longer</p> <p>7 available when the announcement was made?</p> <p>8 A. No, I didn't ask them to do that. I just</p> <p>9 felt like I would use what they already had on hand.</p> <p>10 Q. You didn't do any kind of projection of, I</p> <p>11 think that -- you know -- I anticipate using this many</p> <p>12 products a month and the shelf life is X number of</p> <p>13 years, so I'll need this many products, you didn't do</p> <p>14 that analysis?</p> <p>15 A. No.</p> <p>16 Q. Same question on the Prolift: Do you</p> <p>17 know if any of the hospitals had that device on its</p> <p>18 shelves after Ethicon stopped selling the product?</p> <p>19 A. Yes, they did, and I continued to use it.</p> <p>20 Q. And you used it until they ran out?</p> <p>21 A. That's correct.</p> <p>22 Q. And same question on the Prolift: Did you</p> <p>23 ask any of the hospitals to buy up extra Prolift while</p> <p>24 it was available --</p>

13 (Pages 46 to 49)

Christina Pramudji, M.D.

Page 50	Page 52
<p>1 A. No.</p> <p>2 Q. -- obviously keeping in mind that there's</p> <p>3 an expiration date on the product and you would need</p> <p>4 to use it before it expired?</p> <p>5 A. No, I didn't go to that extent.</p> <p>6 Q. What about the Prolift Plus M device?</p> <p>7 A. Same story.</p> <p>8 Q. Okay. So you did continue to use the Prolift</p> <p>9 Plus M device up until the time it was no longer</p> <p>10 available?</p> <p>11 A. That's correct.</p> <p>12 Q. We talked a little bit about the selection</p> <p>13 criteria you used for the Prosima versus the Prolift</p> <p>14 device. What was your selection criteria for patients</p> <p>15 on the Prolift Plus M device? What kind of patients</p> <p>16 did you put that into?</p> <p>17 A. Well, once the Prolift Plus M became</p> <p>18 available and I felt -- I saw result -- good results</p> <p>19 in my own patients, I started to transition my Prolift</p> <p>20 patients to Prolift Plus M patients. And so I began</p> <p>21 to use it more -- much more frequently than the</p> <p>22 Prolift. And it would have been basically the same</p> <p>23 patients with the more severe prolapse or loss of</p> <p>24 apical support.</p>	<p>1 A. Absolutely. They're great products.</p> <p>2 Q. Do you believe the Prosima device is still</p> <p>3 cleared by the FDA today?</p> <p>4 A. From a regulatory perspective, I'm not sure.</p> <p>5 I don't know.</p> <p>6 Q. If it were not cleared, would you still</p> <p>7 consider implanting the Prosima in a patient?</p> <p>8 MR. GAGE: Object to form.</p> <p>9 A. You know, it worked so great in -- with my</p> <p>10 patients that I probably would consider it, because</p> <p>11 looking at the data and with my own experience, I</p> <p>12 think it's proven to be very effective and safe and I</p> <p>13 feel very comfortable with it.</p> <p>14 Q. (By Mr. Faes) So do you believe a physician</p> <p>15 would be within the standard of care if he knowingly</p> <p>16 implanted a medical device that was not currently cleared</p> <p>17 or approved by the FDA?</p> <p>18 MR. GAGE: Object to form.</p> <p>19 A. In certain situations, yes. Because our</p> <p>20 knowledge as physicians allows us the leeway to use</p> <p>21 things off label.</p> <p>22 Q. (By Mr. Faes) I'm not talking about things</p> <p>23 that aren't indicated. I'm talking about a device</p> <p>24 that is no longer cleared or approved by the FDA.</p>
Page 51	Page 53
<p>1 Q. For the Prolift Plus M?</p> <p>2 A. Correct.</p> <p>3 Q. Did -- was there a time that the Prolift Plus</p> <p>4 M device became your device of choice over the</p> <p>5 Prolift?</p> <p>6 A. Yes, for a while it was.</p> <p>7 Q. Do you recall about what time period that was</p> <p>8 when that occurred?</p> <p>9 A. No, I can't remember.</p> <p>10 Q. You said that you waited to switch over until</p> <p>11 you saw good results in your own patients. Did you do</p> <p>12 -- do you mean you implanted it in the patients and</p> <p>13 then waited to see what happened or are you referring</p> <p>14 to other physicians in your group?</p> <p>15 A. In my own patients --</p> <p>16 Q. Okay.</p> <p>17 A. -- where I could examine them myself and see,</p> <p>18 see how well it worked.</p> <p>19 Q. If you were able to find a Prosima or a</p> <p>20 Prolift device today that was not already expired,</p> <p>21 would you consider implanting it in a patient?</p> <p>22 A. Absolutely.</p> <p>23 Q. Do you believe it's within the standard of</p> <p>24 care to continue to implant those devices today?</p>	<p>1 A. Uh-huh.</p> <p>2 MR. GAGE: Object to form.</p> <p>3 Q. (By Mr. Faes) Do you understand that?</p> <p>4 A. I see the distinction that you're talking</p> <p>5 about. I think strictly legally there could be some</p> <p>6 -- some problems if you implant something that's not</p> <p>7 FDA approved, but whether that's outside the standard</p> <p>8 of care, I think -- I think it could still be within</p> <p>9 the standard of care.</p> <p>10 Q. Backtracking a little bit to the Gynemesh PS</p> <p>11 flat mesh product, have you ever seen the 522 order</p> <p>12 that was issued by the FDA with regard to that</p> <p>13 product?</p> <p>14 A. I believe I have.</p> <p>15 Q. Do you recall, sitting here, what it said?</p> <p>16 A. No, I don't recall.</p> <p>17 Q. Do you know what Ethicon did in response to</p> <p>18 the 522 order on the Gynemesh PS flat mesh?</p> <p>19 A. No, I don't.</p> <p>20 Q. Have you ever used the standard, traditional</p> <p>21 Prolene mesh in your medical practice?</p> <p>22 A. What do you mean by standard, traditional</p> <p>23 Prolene mesh?</p> <p>24 Q. I'm talking about the standard mesh that's</p>

14 (Pages 50 to 53)

Christina Pramudji, M.D.

Page 54	Page 56
<p>1 for hernia repair, not Prolene Soft, not Gynemesh.</p> <p>2 A. No.</p> <p>3 Q. Standard traditional Prolene mesh.</p> <p>4 A. No, I have not.</p> <p>5 Q. Is that a mesh that you would consider using</p> <p>6 in your practice?</p> <p>7 A. I don't know. I'm not familiar with it.</p> <p>8 Q. Let me ask you this: Do you believe it would</p> <p>9 be a reasonable decision for a doctor to stop using</p> <p>10 the Prosima device following the July 2011 FDA public</p> <p>11 health notification?</p> <p>12 A. Sure.</p> <p>13 Q. The same question: Do you believe it would</p> <p>14 be a reasonable decision for a doctor to stop using</p> <p>15 the Prosima -- strike that.</p> <p>16 Do you believe it would be a reasonable</p> <p>17 decision for a doctor to stop using the Prolift or</p> <p>18 Prolift Plus M device following the July 2011 FDA</p> <p>19 public health notification?</p> <p>20 A. If they're uncomfortable with it, that's</p> <p>21 their prerogative.</p> <p>22 Q. Would you agree that surgical complications</p> <p>23 associated with surgical mesh for transvaginal repair</p> <p>24 of pelvic organ prolapse are not rare?</p>	<p>1 Is that correct?</p> <p>2 A. Yes, that's correct.</p> <p>3 Q. Let me ask you this: When you consulted</p> <p>4 patients after this public health notification was</p> <p>5 issued, did you talk to them about this notice?</p> <p>6 A. Absolutely.</p> <p>7 Q. Did you tell your patients that you disagreed</p> <p>8 with the public health notification, that you</p> <p>9 disagreed with the FDA that the complications were not</p> <p>10 rare?</p> <p>11 A. Yes, I did, because in my hands and the</p> <p>12 literature, they are rare.</p> <p>13 Q. Do you believe that a physician, when they --</p> <p>14 a physician who consents is -- strike that.</p> <p>15 If a physician consents his patients for a</p> <p>16 pelvic organ prolapse kit procedure and tells that</p> <p>17 patient that serious complications associated with</p> <p>18 surgical mesh are rare, do you believe that that</p> <p>19 physician has appropriately consented the patient?</p> <p>20 MR. GAGE: Object to form.</p> <p>21 A. Yes.</p> <p>22 Q. (By Mr. Faes) Do you agree or disagree that</p> <p>23 there is no evidence that transvaginal mesh repair</p> <p>24 with mesh provides any added benefit compared to</p>
Page 55	Page 57
<p>1 A. How are you defining "rare"? Or what do you</p> <p>2 mean by "rare"? Can you clarify that?</p> <p>3 Q. Well, you're a physician. How do you</p> <p>4 understand the word "rare" when it relates to</p> <p>5 complications?</p> <p>6 A. In my opinion, and looking at the literature</p> <p>7 and with my own experience, I think that the surgical</p> <p>8 complications are rare, meaning that they're less than</p> <p>9 ten percent.</p> <p>10 (Exhibit No. 8 marked.)</p> <p>11 Q. I'm going to hand you what's been marked as</p> <p>12 Exhibit No. 8 to your deposition. This is the 2011</p> <p>13 public health notification.</p> <p>14 A. Uh-huh.</p> <p>15 Q. If I could have you turn to the second page.</p> <p>16 A. Uh-huh.</p> <p>17 Q. I'm just going to read the -- one, two,</p> <p>18 three, four -- fifth paragraph down. It says: The</p> <p>19 FDA is issuing this update to inform you that serious</p> <p>20 complications associated with surgical mesh for</p> <p>21 transvaginal repair of POP are not rare.</p> <p>22 Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. So you disagree with the FDA in this regard.</p>	<p>1 traditional surgery without mesh?</p> <p>2 A. I disagree, because I think the literature</p> <p>3 bears it out, but the transvaginal mesh repair is more</p> <p>4 effective than traditional repair. There's multiple</p> <p>5 studies that reinforce that.</p> <p>6 Q. And you know --</p> <p>7 A. And I saw that in my own experience.</p> <p>8 Q. And if you turn to Page 3, you see that that</p> <p>9 statement is contained within the public health</p> <p>10 notification, as well.</p> <p>11 A. (No response.)</p> <p>12 Q. It's the third bullet point. I'll read it</p> <p>13 again for you. There is no evidence that transvaginal</p> <p>14 repair to support the top of the vagina, parentheses,</p> <p>15 (apical repair or back wall of the vagina),</p> <p>16 parentheses, posterior repair with mesh provides any</p> <p>17 added benefit compared to traditional surgery without</p> <p>18 mesh.</p> <p>19 Do you see that?</p> <p>20 A. Yes, I do.</p> <p>21 Q. And you disagree with that statement from the</p> <p>22 FDA?</p> <p>23 A. When you narrow in on the posterior wall, it</p> <p>24 is not as much of a benefit as it is on the anterior</p>

15 (Pages 54 to 57)

Christina Pramudji, M.D.

Page 58	Page 60
<p>1 wall, which is what I was referring to previously.</p> <p>2 Q. So I'm not sure if I got an answer to my</p> <p>3 question. Are you saying you agree with this</p> <p>4 statement from the FDA or disagree with it or you</p> <p>5 can't answer?</p> <p>6 A. I would agree with that bullet point --</p> <p>7 Q. When you --</p> <p>8 A. -- about the posterior wall.</p> <p>9 Q. When you consented patients for pelvic organ</p> <p>10 prolapse procedures after July of 2013 --</p> <p>11 A. Uh-huh.</p> <p>12 Q. -- did you tell them that there was no</p> <p>13 evidence that using mesh provides any added benefit as</p> <p>14 compared to traditional surgery without a mesh?</p> <p>15 MR. GAGE: Object to form.</p> <p>16 A. What I told patients -- we're speaking of a</p> <p>17 posterior repair right now. And what I told patients</p> <p>18 is that there is a slight benefit with the mesh and</p> <p>19 there is definitely a benefit with decreased pain with</p> <p>20 the posterior mesh versus a traditional posterior</p> <p>21 plication repair. Does that answer your question?</p> <p>22 Q. (By Mr. Faes) Yes. Do you agree that mesh</p> <p>23 used in transvaginal pelvic organ prolapse repair</p> <p>24 introduces risks not present in traditional non-mesh</p>	<p>1 20th, 2008 public health notification.</p> <p>2 So at least according to this, both the FDA</p> <p>3 and the medical literature believed that mesh</p> <p>4 contraction or shrinkage does exist. Is that correct?</p> <p>5 MR. GAGE: Object to form.</p> <p>6 A. Yes, they do believe that, but I respectfully</p> <p>7 disagree, because the mesh does not contract. It's</p> <p>8 the scar tissue around it. And you can see wound</p> <p>9 contraction and vaginal shortening, tightening, pain</p> <p>10 with any pelvic floor correction.</p> <p>11 Q. (By Mr. Faes) So you would disagree with</p> <p>12 both the FDA and the medical literature that mesh</p> <p>13 can contract or shrink?</p> <p>14 MR. GAGE: Object to form.</p> <p>15 A. Yes, the mesh does not contract or shrink.</p> <p>16 The wound and the scarring is what contracts and</p> <p>17 shrinks. The mesh, itself, does not.</p> <p>18 Q. (By Mr. Faes) When the wound or scar</p> <p>19 contracts and shrinks --</p> <p>20 A. Uh-huh.</p> <p>21 Q. -- if the mesh is encapsulated --</p> <p>22 A. Uh-huh.</p> <p>23 Q. -- can the mesh shrink, as well, along with</p> <p>24 the wound or scar tissue?</p>
Page 59	Page 61
<p>1 surgery for pelvic organ prolapse repair?</p> <p>2 A. The only additional risk that it introduces</p> <p>3 is a mesh exposure.</p> <p>4 Q. So was my -- the answer to my question, yes,</p> <p>5 you agree with that statement?</p> <p>6 A. (No response.)</p> <p>7 Q. Do you want me to read the question again?</p> <p>8 MR. GAGE: No. She can look at it here.</p> <p>9 A. No. It only introduces that one risk. All</p> <p>10 the other risks are going to be potential with any</p> <p>11 pelvic floor surgery.</p> <p>12 Q. (By Mr. Faes) So is it your testimony that</p> <p>13 mesh contraction is a risk of any other pelvic</p> <p>14 surgery?</p> <p>15 A. Wound contraction is. Mesh doesn't contract.</p> <p>16 The wound contracts and the scarring contracts.</p> <p>17 Q. You don't believe that mesh contracts?</p> <p>18 A. No. The wound and the scar contract.</p> <p>19 Q. If you go down to the second paragraph below</p> <p>20 the bullet point it says: Mesh contraction,</p> <p>21 parenthesis, (shrinkage) is a previously unidentified</p> <p>22 risk of transvaginal POP repair with mesh that has</p> <p>23 been reported in the scientific literature in an</p> <p>24 adverse event reports to the FDA since the October</p>	<p>1 A. I mean, it's a matter of semantics. The</p> <p>2 mesh, itself, is not shrinking or contracting. If you</p> <p>3 take it out, it's going to be the same Prolene caliber</p> <p>4 fibers. They're not going to be shrunken.</p> <p>5 Q. There not going to be shrunken or deformed as</p> <p>6 the wound or the scar tissue which completely</p> <p>7 surrounds it contracts?</p> <p>8 A. The pores will be -- the pores of the mesh</p> <p>9 maybe shrunken or deformed and pulled together by the</p> <p>10 scar tissue, but the Prolene, itself, is not shrunken.</p> <p>11 Q. Do you degree -- strike that.</p> <p>12 Do you agree or disagree that mesh placed</p> <p>13 abdominally for pelvic organ prolapse repair results</p> <p>14 in lower rates of mesh complications compared to</p> <p>15 transvaginal pelvic organ prolapse surgery with mesh?</p> <p>16 A. Actually, the mesh erosion rates are similar</p> <p>17 with the transabdominal and the transvaginally placed</p> <p>18 mesh looking at the sacrocolpopexy studies. They have</p> <p>19 similar rates.</p> <p>20 Q. So if you turn to Page 4 of exhibit -- the</p> <p>21 exhibit that I just handed you.</p> <p>22 A. (Complying.)</p> <p>23 Q. You go under the bullet point: Consider</p> <p>24 these factors before placing surgical mesh. The last</p>

Christina Pramudji, M.D.

Page 62	Page 64
<p>1 bullet point you see, it reads: Mesh placed</p> <p>2 abdominally for pelvic organ prolapse repair may</p> <p>3 result in lower rates of mesh complications compared</p> <p>4 to transvaginal pelvic organ prolapse surgery with</p> <p>5 mesh.</p> <p>6 Is it fair to say that you disagree with the</p> <p>7 FDA on this statement?</p> <p>8 A. Well, it says it may result. They're not</p> <p>9 saying it does result in lower rates. And I think, if</p> <p>10 we look at the literature, we can see they're very</p> <p>11 similar rates.</p> <p>12 Q. So you -- does that mean you agree with the</p> <p>13 statement from the FDA that it may result in lower</p> <p>14 rates of mesh complications compared to transvaginal</p> <p>15 pelvic organ prolapse surgery with mesh?</p> <p>16 A. As they've written it here, may result, I</p> <p>17 can't really disagree with that. I think, as -- as</p> <p>18 time has borne out and as we've seen further studies</p> <p>19 with sacrocolpopexy, we're seeing that this -- the</p> <p>20 mesh exposure rate is very similar or suture exposure</p> <p>21 rate. And with abdominally placed mesh you also have</p> <p>22 the risk of bowel obstruction and adhesions,</p> <p>23 intraabdominal adhesions.</p> <p>24 Q. I think you've answered my question. I'll</p>	<p>1 which studied whether or not the product was effective</p> <p>2 for -- strike that.</p> <p>3 Do you agree that native tissue repairs have</p> <p>4 similar outcomes to synthetic mesh without the risks</p> <p>5 inherent in mesh use?</p> <p>6 MR. GAGE: Object to form.</p> <p>7 A. (No response.)</p> <p>8 Q. (By Mr. Faes) Why don't I ask a better</p> <p>9 question? Do you agree that native tissue repairs for</p> <p>10 the repair of pelvic organ prolapse have similar</p> <p>11 outcomes to synthetic mesh used for pelvic organ</p> <p>12 prolapse without the risks inherent in mesh use?</p> <p>13 A. No.</p> <p>14 MR. GAGE: Object to form.</p> <p>15 A. I think the -- in my opinion, the literature</p> <p>16 is clear that the outcomes are better with mesh</p> <p>17 augmentation and the risks are similar. The only</p> <p>18 additional risk is mesh exposure or erosion.</p> <p>19 Q. (By Mr. Faes) Do you agree or disagree that</p> <p>20 native tissue repair remains the standard of care for</p> <p>21 the treatment of pelvic organ prolapse in the typical</p> <p>22 patient?</p> <p>23 A. I disagree. The standard of care is</p> <p>24 sacrocolpopexy at this point.</p>
Page 63	Page 65
<p>1 object to move to strike after the word "that" just</p> <p>2 for the record.</p> <p>3 If a synthetic graft product like the Prosima</p> <p>4 does not do better than native tissue repair, in terms</p> <p>5 of safety and efficacy, do you think it should be</p> <p>6 introduced to the market?</p> <p>7 A. That's a hypothetical question.</p> <p>8 Q. It is.</p> <p>9 A. If any product doesn't show improved safety</p> <p>10 or efficacy, I don't know why they would want to --</p> <p>11 why anyone would want to release it or market it.</p> <p>12 What would be the point?</p> <p>13 Q. Okay. Do you agree or disagree with the</p> <p>14 following statement: There is no authoritative --</p> <p>15 authoritative paper to support the Prosima outcomes</p> <p>16 are superior or even comparable to a colporrhaphy?</p> <p>17 A. I disagree with that statement.</p> <p>18 Q. So if the investigator of a -- on a Prosima</p> <p>19 trial were to make that statement to Ethicon, you</p> <p>20 would disagree with that statement?</p> <p>21 A. Yes. I think we've got some good literature</p> <p>22 that shows that it is efficacious and safe. And</p> <p>23 that's also what I saw in my own experience.</p> <p>24 Q. If a primary investigator for a Prosima trial</p>	<p>1 Q. What exhibit are we on, Doctor? Are we on 9?</p> <p>2 A. 8. It's 9.</p> <p>3 MR. GAGE: This was one 8.</p> <p>4 A. That's correct.</p> <p>5 MR. GAGE: So 9 would be next.</p> <p>6 (Exhibit No. 9 marked.)</p> <p>7 Q. (By Mr. Faes) Doctor, I'm going to hand you</p> <p>8 what's been marked as Exhibit 9 to your deposition.</p> <p>9 MR. FAES: I actually got one of these</p> <p>10 for you, too, William.</p> <p>11 Q. (By Mr. Faes) Give you a second to review</p> <p>12 that. And my first question is: Have you seen this</p> <p>13 document before?</p> <p>14 A. Yes, I have.</p> <p>15 Q. Is this a document that you reviewed and</p> <p>16 relied upon in forming your opinions in this case?</p> <p>17 A. Yes.</p> <p>18 Q. Do you agree that -- let me read this. This</p> <p>19 is a document titled FDA strengthens -- strengthens</p> <p>20 requirement for surgical mesh for the transvaginal</p> <p>21 repair of pelvic organ prolapse to address safety</p> <p>22 risks. And it's dated January 4th, 2016.</p> <p>23 Do you see that?</p> <p>24 A. Yes.</p>

17 (Pages 62 to 65)

Christina Pramudji, M.D.

Page 66	Page 68
<p>1 Q. It says beginning in the first paragraph,</p> <p>2 second sentence: The FDA issued one order to</p> <p>3 reclassify these medical devices from class II, which</p> <p>4 generally includes moderate-risk devices, to class</p> <p>5 III, which generally includes high-risk devices.</p> <p>6 Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. Do you agree that surgical mesh to repair</p> <p>9 pelvic organ prolapse are high-risk devices?</p> <p>10 A. No, I don't agree.</p> <p>11 Q. So do you disagree with the FDA's decision to</p> <p>12 reclassify surgical mesh to a high-risk device?</p> <p>13 A. Yes, I do.</p> <p>14 Q. Do you believe that the Prosima is a</p> <p>15 high-risk device?</p> <p>16 A. No, not at all.</p> <p>17 Q. Do you believe that the Prolift is a</p> <p>18 high-risk device?</p> <p>19 A. No, not at all.</p> <p>20 Q. Do you believe the Gynemesh PS flat mesh is a</p> <p>21 high-risk device?</p> <p>22 A. No.</p> <p>23 Q. Do you know whether or not the Prolift is now</p> <p>24 classified as a class III -- strike that.</p>	<p>1 Q. And you don't know obviously, then, if the</p> <p>2 number of this residual risk score correlates to the</p> <p>3 device being low risk, moderate risk or high risk?</p> <p>4 A. I don't know.</p> <p>5 Q. And, again, since you've never seen these,</p> <p>6 you don't know what Ethicon's assessment was for the</p> <p>7 Prolift, Prosima or the Gynemesh PS flat mesh with</p> <p>8 regards to whether it was a low, moderate or high-risk</p> <p>9 device. Is that correct?</p> <p>10 A. That's correct.</p> <p>11 Q. Now, if you look again at Exhibit No. 9, on</p> <p>12 the very first paragraph it says: Surgical mesh has</p> <p>13 been used by surgeons since the 1950s to repair</p> <p>14 abdominal hernias; in the 1970s, gynecologists began</p> <p>15 implanting surgical mesh for abdominal repair of</p> <p>16 pelvic organ prolapse and, in the 1990s, for</p> <p>17 transvaginal repair of pelvic organ prolapse. In</p> <p>18 2002, the first flat mesh device with this indication</p> <p>19 was cleared for use as a class II moderate risk</p> <p>20 device.</p> <p>21 Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. Do you know whether or not that the first</p> <p>24 mesh device with this indication that was cleared in</p>
Page 67	Page 69
<p>1 Do you know whether or not the Gynemesh PS</p> <p>2 flat mesh is now classified as a class III or class II</p> <p>3 device?</p> <p>4 A. I don't know.</p> <p>5 Q. Do you think that would be important in -- or</p> <p>6 something you'd like to consider in forming your</p> <p>7 opinions regarding the Gynemesh PS?</p> <p>8 A. No. I feel very comfortable with it with my</p> <p>9 experience and with the literature.</p> <p>10 Q. Do you know whether or not Ethicon does</p> <p>11 internal risk analysis to determine risk scores for</p> <p>12 those devices -- strike that. I think I phrased that</p> <p>13 wrong.</p> <p>14 Do you know whether or not Ethicon does</p> <p>15 internal risk analysis to determine risk scores for</p> <p>16 the medical devices they sell?</p> <p>17 A. I'm not sure.</p> <p>18 Q. You've never seen a residual risk analysis</p> <p>19 for the Prosima, Prolift or Gynemesh PS device?</p> <p>20 A. I don't think I have.</p> <p>21 Q. So you don't recall, sitting here today,</p> <p>22 whether or not Ethicon assigns a residual risk score</p> <p>23 when they do these analyses. Is that correct?</p> <p>24 A. That's correct.</p>	<p>1 2002 that it's referring to is the Gynemesh PS?</p> <p>2 A. I don't know.</p> <p>3 Q. So you don't know, sitting here today,</p> <p>4 whether or not the Gynemesh PS flat mesh was the first</p> <p>5 mesh device which was cleared with a transvaginal use</p> <p>6 indication?</p> <p>7 A. I know it -- I think that was the year that</p> <p>8 it was approved and cleared, but I don't know if it</p> <p>9 was the first one.</p> <p>10 Q. Good enough. Do you know if Ethicon wanted</p> <p>11 to sell the Gynemesh PS flat mesh with a transvaginal</p> <p>12 use indication today, if they would have to submit a</p> <p>13 premarket approval indication to the FDA because it's</p> <p>14 now a class III device?</p> <p>15 A. Can you repeat your question, please?</p> <p>16 Q. You know what, I'm going to strike that --</p> <p>17 A. Okay.</p> <p>18 Q. -- and move on. Doctor, on Page 3 of your</p> <p>19 report -- and feel free to refer back to it if you</p> <p>20 want. It's already marked as an exhibit. -- you</p> <p>21 state that the data in women does not support that the</p> <p>22 Gynemesh Prolene Soft degrades. Is that an opinion</p> <p>23 you intend to offer in this case?</p> <p>24 A. Absolutely. I feel very strongly about that.</p>

18 (Pages 66 to 69)

Christina Pramudji, M.D.

Page 70	Page 72
<p>1 Q. Would you agree that you are not an expert in 2 polymer chemistry?</p> <p>3 A. No, I would not agree with that. I mean, I 4 have dealt with polymers all these years as a surgeon 5 and I was a chemical engineering undergrad and studied 6 polymer science there, so I feel comfortable with 7 polymers and I understand how Gynemesh works in 8 patients in over 2000 patients.</p> <p>9 Q. So you hold yourself out as an expert in 10 polymer chemistry. Is that right?</p> <p>11 A. Yes, as far as it -- as far as it relates to 12 my practice, I certainly do.</p> <p>13 Q. Have you ever done any chemical testing with 14 the Prolene Soft mesh or the mesh in the Prolift or 15 the Prosima to see if it degrades?</p> <p>16 A. No, I haven't done that.</p> <p>17 Q. Have you ever done a microscopic analysis of 18 the Prolene Soft mesh or the mesh that's in the -- 19 which is the mesh that's in the Prolift or in Prosima 20 to determine if it degrades?</p> <p>21 A. No, I haven't.</p> <p>22 Q. Do you -- strike that.</p> <p>23 In support of your opinion regarding mesh 24 degradation you state that the reoperation rates for</p>	<p>1 A. For mesh failure -- what do you mean by "mesh 2 failure"? Do you mean that the prolapse occurred?</p> <p>3 Q. Yes.</p> <p>4 A. In that same compartment or in another 5 compartment?</p> <p>6 Q. Well, let's -- both questions. What 7 do you believe the reoperation rates are for Prolift 8 for prolapse recurring in the same compartment, 9 different compartment, and then both combined?</p> <p>10 A. It's going to be -- for the -- the -- it's 11 going to be around 20 percent per compartment.</p> <p>12 Q. So I'm not sure if that answered my question, 13 so I'll break it down. What do you believe are 14 reoperation rates for Prosima for failures in the same 15 compartment?</p> <p>16 A. For a recurrent -- I don't call it a mesh 17 failure, first of all, because it's not necessarily a 18 fault of the mesh. It's just the way that the pelvis 19 is. There's going to be a certain degree of recurrent 20 prolapse no matter what technique you use.</p> <p>21 Q. Let me see if I can re-ask the question in a 22 way that you can answer with a straight percentage. 23 What do you believe the reoperation rates are for the 24 Prosima for treatment failure in the same compartment?</p>
Page 71	Page 73
<p>1 recurrence are low and that cure rates and patient 2 satisfaction is high. Is there anything else you 3 believe supports your opinion?</p> <p>4 A. Well, the literature definitely supports it 5 when we don't see problems that can be related back to 6 degradation in the literature.</p> <p>7 Q. What do you believe the reoperation rates are 8 for the Prosima device?</p> <p>9 A. Oh, five percent, ten percent. And most of 10 those are just small erosions that need to be 11 repaired.</p> <p>12 Q. What do you --</p> <p>13 MR. GAGE: Object to form of the last 14 question. I think you asked a question and the 15 witness give a different answer, so that's all I'm 16 saying.</p> <p>17 Q. (By Mr. Faes) What do you believe the --</p> <p>18 MR. FAES: Yeah, I think she answered 19 about complications, not reoperation, so maybe I asked 20 a bad question.</p> <p>21 Q. (By Mr. Faes) What do you believe the 22 reoperation rates -- strike that.</p> <p>23 What do you believe the reoperation rates are 24 for Prosima for mesh failure?</p>	<p>1 A. Okay. So it's somewhere between ten to 20 2 percent.</p> <p>3 Q. What do you believe the reoperation rates are 4 for the Prosima for treatment failure in a different 5 compartment?</p> <p>6 A. About the same.</p> <p>7 Q. What do you believe the reoperation rates are 8 for the Prosima for treatment failure either in the 9 same compartment or a different compartment?</p> <p>10 A. It would be --</p> <p>11 MR. GAGE: Object the form.</p> <p>12 A. -- about the same, around that --</p> <p>13 Q. (By Mr. Faes) Ten to 20 percent?</p> <p>14 A. Around that range, yeah.</p> <p>15 Q. And I think you already anticipated my 16 question and answered it, but what do you believe the 17 reoperation rates are for Prosima for mesh extrusion 18 or -- strike that. I'm going to ask it a little bit 19 different question.</p> <p>20 What do you believe the reoperation rates are 21 for the Prosima to treat complications, all 22 complications, excluding treatment failure?</p> <p>23 A. Excluding treatment failure, somewhere 24 between five and ten percent.</p>

19 (Pages 70 to 73)

Christina Pramudji, M.D.

Page 74	Page 76
<p>1 Q. What do you believe the reoperation rates are</p> <p>2 for the Prosima to treat complications or treatment</p> <p>3 failure in any compartment?</p> <p>4 A. So somewhere between five and 20 percent.</p> <p>5 That's looking at the literature, looking at my own</p> <p>6 experience.</p> <p>7 Q. So you -- as you sit here today, you don't</p> <p>8 believe that a reoperation rate for treatment failure</p> <p>9 of ten to 20 percent and a reoperation rate for</p> <p>10 complications of five to ten percent is evidence that</p> <p>11 the Gynemesh PS mesh in the Prosima degrades?</p> <p>12 A. No, not at all. There's no correlation</p> <p>13 there.</p> <p>14 Q. Is there a number it would reach -- it could</p> <p>15 reach in order for you to change or reconsider your</p> <p>16 opinion that the data in women doesn't support that</p> <p>17 the Gynemesh PS degrades?</p> <p>18 A. I can't -- I can't even conceive of that,</p> <p>19 because it does not even -- it does not degrade in any</p> <p>20 way, so it's just a hypothetical question. So, yes,</p> <p>21 there's no --</p> <p>22 Q. So if there --</p> <p>23 A. There's nothing you could tell me that would</p> <p>24 make me say, oh, that's because of degradation,</p>	<p>1 support of your opinion that the data in women does</p> <p>2 not support that the Gynemesh PS degrades, you state</p> <p>3 that the reoperation rates for recurrence are low,</p> <p>4 that the cure rates and patient satisfaction are high.</p> <p>5 Is there anything else that you're relying on to</p> <p>6 support your opinion that the data in women does not</p> <p>7 support that the Gynemesh PS degrades?</p> <p>8 A. Well, also, apart from these, sort of, side</p> <p>9 studies where they show, quote, unquote, degradation,</p> <p>10 which I think is just probably the biofilm, in other</p> <p>11 studies, where they -- where they remove the mesh, the</p> <p>12 mesh is there. You know, it's not -- it doesn't</p> <p>13 disappear. It doesn't degrade over time. I mean, if</p> <p>14 Prolene degraded, they would not use it in cardiac</p> <p>15 surgery to rely on sewing together arteries. So this</p> <p>16 whole theory of degradation is just -- just bogus in</p> <p>17 my opinion.</p> <p>18 Q. So if I understand you correctly, you're</p> <p>19 relying on literature to support your opinion that the</p> <p>20 Gynemesh PS doesn't degrade?</p> <p>21 A. And my own clinical experience, my own</p> <p>22 clinical experience with my patient success and</p> <p>23 satisfaction with it. And in the cases where I've</p> <p>24 removed mesh, you know, grossly examining the mesh --</p>
Page 75	Page 77
<p>1 because it doesn't happen.</p> <p>2 Q. But if I understand you correctly, you're</p> <p>3 using the -- you rely on the fact that reoperation</p> <p>4 rates for recurrence are low and cure rates and</p> <p>5 patient satisfaction is high is the basis for</p> <p>6 your opinion that the mesh doesn't degrade.</p> <p>7 Right?</p> <p>8 A. Right.</p> <p>9 Q. So you're saying -- telling me that there's</p> <p>10 no number that that -- that those reoperation rates</p> <p>11 could rise to that would cause you to reconsider your</p> <p>12 opinion?</p> <p>13 A. No. I mean, that's part of the basis.</p> <p>14 That's not the whole basis. That's just -- first of</p> <p>15 all, we're starting with the fact that it doesn't</p> <p>16 degrade and then this is the supportive reason to show</p> <p>17 that it doesn't. But the converse is not necessarily</p> <p>18 true. If this happens, that doesn't mean that it</p> <p>19 degrades, if that makes sense.</p> <p>20 Q. So, again, I think I asked you this</p> <p>21 question earlier -- maybe I didn't or maybe I've</p> <p>22 already forgotten the experts that your -- strike</p> <p>23 that. I'm just babbling now.</p> <p>24 So let me just ask you a new question: In</p>	<p>1 yeah, I didn't do a microscopic electron microscopy on</p> <p>2 the mesh, but, you know, it's not like you see it</p> <p>3 disintegrating. It's not falling apart in front of</p> <p>4 your eyes.</p> <p>5 Q. Have -- or do you believe that the mesh has</p> <p>6 to be disintegrating for falling apart in front of</p> <p>7 your eyes in order to have a clinical impact on the</p> <p>8 patient? Do you believe -- strike that. Let me ask a</p> <p>9 different question.</p> <p>10 Do you believe that -- actually, let me start</p> <p>11 over.</p> <p>12 Do you believe that polypropylene doesn't</p> <p>13 degrade at all or do you just believe that the</p> <p>14 polypropylene mesh in the pelvic organ prolapse</p> <p>15 products that you're offering opinion on -- opinions</p> <p>16 on don't grade?</p> <p>17 MR. GAGE: Object to form.</p> <p>18 A. I don't think it degrades at all. If it does</p> <p>19 degrade, microscopically, there's absolutely no</p> <p>20 clinical effect on patients --</p> <p>21 Q. (By Mr. Faes) So your --</p> <p>22 A. -- and there's no implication to it.</p> <p>23 Q. Your opinion is that no polypropylene</p> <p>24 anywhere degrades?</p>

20 (Pages 74 to 77)

Christina Pramudji, M.D.

Page 78	Page 80
<p>1 A. Like I said, if it does degrade, 2 microscopically, there's no clinical impact, so it's a 3 nonissue. 4 Q. I'm not sure if I got an answer to my 5 question, though. Is it your opinion that no 6 polypropylene anywhere degrades or do you agree that 7 some polypropylene can degrade under the right 8 circumstances? 9 A. I think it potentially could degrade under 10 the right circumstances. Anything can degrade under 11 the right circumstances. But does it clinically have 12 any impact, no. 13 Q. Do you believe that when polypropylene mesh 14 degrades, it can become -- strike that. 15 Do you believe that when polypropylene 16 degrades one of the things that can occur is that the 17 polypropylene can become brittle? 18 MR. GAGE: Object to form. 19 A. No. 20 Q. (By Mr. Faes) Do you know what fishing line 21 is made out of? 22 A. No, I don't. 23 Q. You don't know that fishing line is made out 24 of polypropylene?</p>	<p>1 A. Not to the same degree. 2 Q. (By Mr. Faes) Do you know whether peroxides 3 have an effect on polypropylene degradation? 4 A. I believe that they can, yes. 5 Q. So, just so I understand your answer, you do 6 believe that peroxides can accelerate or cause 7 polypropylene to degrade? 8 A. In the right concentration, yes. 9 Q. What do you believe the patient satisfaction 10 rates are for the Prosima device? 11 A. They're very high. They're 80 to 90 percent. 12 Q. And where are you getting that information 13 from? 14 A. From multiple studies. 15 Q. What do you believe the reoperation rates are 16 for the Prolift device for complications? 17 A. It's around the same as the Prosima, five to 18 20 percent. 19 Q. That's a pretty big range, isn't it, Doctor? 20 A. Yeah, and the studies are -- that's pretty 21 much the range that you're going to find in the 22 studies. 23 Q. Would you agree that the erosion or extrusion 24 rate for the Prolift can range from 15 to 20 percent?</p>
Page 79	Page 81
<p>1 A. No, I didn't know that. 2 Q. Have you ever gone fishing? 3 A. Yes. 4 Q. Have you ever had to replace your fishing 5 line because the line got brittle from the previous 6 year? 7 A. Yes. But that's a completely different 8 circumstance than something that's implanted in the 9 body. 10 Q. Well, I wasn't asking about things that were 11 implanted in the body. I'm asking -- so you'd agree 12 with that example, that polypropylene under the right 13 circumstances can degrade? 14 A. Yeah, sure. 15 Q. You also talked about the fact that 16 polypropylene sutures are used -- or Prolene sutures, 17 rather, are used in cardiac surgery. Do you believe 18 that the environment in the vagina is the same as the 19 environment in the cardiac cavity? 20 A. No. It's different. 21 Q. In fact, you know that there are peroxides 22 present in the vagina and there are not peroxides 23 present in the cardiac cavity. Right? 24 MR. GAGE: Object to form.</p>	<p>1 A. Some studies show that, but most studies it's 2 closer to the five to ten percent range. Eight 3 percent seems to be the number that comes up a lot. 4 Q. So you did -- if someone were to tell you 5 that the overall erosion or exposure or extrusion 6 rates for the Prolift was in the 15 to 20 percent 7 range, you'd disagree with that? 8 A. Yeah. That's -- that's high. I know some 9 studies have shown that and have shown even higher in 10 small studies, but -- but looking at the large 11 database studies, the rates are not that high. 12 Q. Do you know Dr. Joe Carbone? 13 A. Yes. 14 Q. You've met Dr. Joe Carbone -- 15 A. I have. 16 Q. -- before. Right? In fact, you both 17 attended the 2011 Ethicon Pelvic Floor Summit in 18 Sonoma together? 19 A. Yes. 20 Q. Where there was wine tasting and dinner? 21 A. Yes. 22 Q. So if Dr. Carbone told me last week that he 23 believes the overall erosion or extrusion rates for 24 the Prolift device is 15 to 20 percent, would you</p>

21 (Pages 78 to 81)

Christina Pramudji, M.D.

Page 82	Page 84
<p>1 disagree with him?</p> <p>2 A. With all due respect to Dr. Carbone, I think</p> <p>3 -- I don't think the literature bears out that -- that</p> <p>4 high a rate. And my personal experience certainly is</p> <p>5 not that high. And I think, talking to my colleagues,</p> <p>6 it's not that high.</p> <p>7 Q. But you do agree that, at least in some</p> <p>8 studies, the erosion or exposure rate can be as high</p> <p>9 as 20 percent with the Prolift. Right?</p> <p>10 A. I have seen studies that show that yes.</p> <p>11 Q. And you're familiar with the Iglesia study?</p> <p>12 A. Yes.</p> <p>13 Q. And you know that the exposure and erosion</p> <p>14 rate for the Prolift in that study was greater than 15</p> <p>15 percent?</p> <p>16 A. Yes, as well as the suture exposure rate was</p> <p>17 also 15 percent in the native tissue repairs.</p> <p>18 MR. FAES: I'm going to object and move</p> <p>19 to strike after the answer "yes." I didn't ask</p> <p>20 anything about suture exposure rates.</p> <p>21 Q. (By Mr. Faes) And you know that that study</p> <p>22 was stopped by Dr. Iglesia and her colleagues because</p> <p>23 of their concern about the erosion and exposure rates.</p> <p>24 Correct?</p>	<p>1 literature with my own experience and that's where I</p> <p>2 form my opinions, so I would have to disagree with</p> <p>3 them on that.</p> <p>4 Q. (By Mr. Faes) Yeah. I'm going to have to</p> <p>5 re-ask it, because there's a lot of nonresponsive</p> <p>6 information in there. I'm going to ask a</p> <p>7 hypothetical: Assuming that the FDA said that they</p> <p>8 did not consider Dr. Iglesia an outlier, if they did</p> <p>9 indeed say that, that's another instance in which you</p> <p>10 would disagree with the FDA. Is that correct?</p> <p>11 A. That's correct.</p> <p>12 MR. GAGE: Object to form.</p> <p>13 Q. (By Mr. Faes) What do you believe are the</p> <p>14 patient satisfaction rates with the Prolift device?</p> <p>15 A. Again, very high, 75 to 90 percent.</p> <p>16 Q. At what time frame? Are you calculating</p> <p>17 patient satisfaction rates at one year, three years?</p> <p>18 A. Well, the -- you know -- studies go -- most</p> <p>19 -- a lot -- most of the studies are one to two years,</p> <p>20 but there are some studies that go out further to</p> <p>21 seven years.</p> <p>22 Q. What's the longest study that you're aware</p> <p>23 of, the longest follow-up study you're aware of that</p> <p>24 utilized the Gynemesh PS mesh, whether it be in the</p>
Page 83	Page 85
<p>1 A. That's correct.</p> <p>2 Q. Do you consider Dr. Iglesia an outlier?</p> <p>3 A. Yes, I do.</p> <p>4 Q. Do you know whether the FDA considers Dr.</p> <p>5 Iglesia and outlier?</p> <p>6 A. I don't know what they think about</p> <p>7 Dr. Iglesia.</p> <p>8 Q. So you've never seen records from meetings</p> <p>9 that Ethicon had with the FDA regarding the 522 orders</p> <p>10 where the FDA told Ethicon that they did not consider</p> <p>11 Dr. Iglesia an outlier. Is that fair?</p> <p>12 MR. GAGE: Object to form.</p> <p>13 A. You know, I've seen so many documents. As I</p> <p>14 sit here today, I'm not sure if I saw that or not. I</p> <p>15 probably did.</p> <p>16 Q. (By Mr. Faes) So I'm going to ask a</p> <p>17 hypothetical: Assuming that the FDA said that they</p> <p>18 did not consider Dr. Iglesia an outlier, that's</p> <p>19 another instance in which you would agree with --</p> <p>20 disagree with the FDA. Correct?</p> <p>21 MR. GAGE: Object the form.</p> <p>22 A. With all due respect to the FDA and</p> <p>23 Dr. Iglesia, I look at the full body of literature. I</p> <p>24 don't look at one study. I compare the full body of</p>	<p>1 Prolift or the Prosima or as a flat mesh?</p> <p>2 A. I believe it's seven years.</p> <p>3 Q. Do you recall what study or studies go out to</p> <p>4 seven years?</p> <p>5 A. I would have to take a minute to refresh my</p> <p>6 memory.</p> <p>7 Q. Do you recall, without refreshing your</p> <p>8 memory, whether it's more than one or if it's. . .</p> <p>9 A. I believe there were two studies.</p> <p>10 Q. Do you believe that if polypropylene mesh</p> <p>11 were to break down or degrade, it could lead to an</p> <p>12 erosion or an exposure?</p> <p>13 A. We're talking hypothetically. And I would</p> <p>14 think that if it were degrading, then it would be just</p> <p>15 disappearing. And so I'm not sure how that could</p> <p>16 cause an erosion or an exposure.</p> <p>17 Q. Do you believe that mesh degrading or</p> <p>18 breaking down could lead to an unintended tissue</p> <p>19 reaction?</p> <p>20 A. Again, hypothetically, because as I stated</p> <p>21 before, I don't think it does degrade, but if there's</p> <p>22 some product that did degrade, then, yes, that could</p> <p>23 cause an inflammatory reaction.</p> <p>24 Q. Can an inflammatory reaction or unintended</p>

22 (Pages 82 to 85)

Christina Pramudji, M.D.

Page 86	Page 88
<p>1 tissue reaction cause the body to push the mesh out of</p> <p>2 the body causing it to be eroded or exposed?</p> <p>3 A. Hypothetically, if there's an inflammatory</p> <p>4 reaction, you could have a tissue breakdown and have a</p> <p>5 mesh exposure. I wouldn't say it's pushing it out of</p> <p>6 the body, but there could -- if there's a tissue</p> <p>7 breakdown, you could have an exposure of the mesh.</p> <p>8 Q. If polypropylene were to become brittle, as</p> <p>9 we discussed with the fishing line example, could that</p> <p>10 lead to an erosion?</p> <p>11 A. I think it would depend on how it how it --</p> <p>12 how it were oriented. And, again, I'm not conceding</p> <p>13 that it degrades or becomes brittle in the body. But</p> <p>14 hypothetically, if it were poking out towards the</p> <p>15 tissue, something could break down, I suppose.</p> <p>16 Q. You'd agree that sharp edges of the mesh</p> <p>17 could cause an erosion?</p> <p>18 A. If the mesh is not oriented properly and not</p> <p>19 placed properly, that could cause an erosion from a</p> <p>20 sharp edge. It's not because of the mesh. It's the</p> <p>21 way that it's put in.</p> <p>22 Q. If the mesh becomes -- hypothetically, again,</p> <p>23 if the mesh becomes brittle, could that lead to</p> <p>24 patient discomfort?</p>	<p>1 Gynemesh, Prolift and Prosima.</p> <p>2 Q. So, approximately, how many studies did you</p> <p>3 determine had been done on the Vypro mesh in pelvic</p> <p>4 reconstructive surgery?</p> <p>5 A. I don't -- I don't have a number, but it's</p> <p>6 not many at all.</p> <p>7 Q. How many studies did you find where PD</p> <p>8 -- PVDF mesh had been studied in pelvic reconstructive</p> <p>9 surgery?</p> <p>10 A. I don't have a number.</p> <p>11 Q. How many Ultrapro studies did you find that</p> <p>12 had been studied in pelvic reconstructive surgery?</p> <p>13 A. I don't have a number for that.</p> <p>14 Q. How many Elevate studies did you find that</p> <p>15 had been studied in pelvic reconstructive surgery?</p> <p>16 A. I'm sorry. I don't have an exact number.</p> <p>17 Q. So you can't quote a number as you're sitting</p> <p>18 here today, but you believe it's less?</p> <p>19 A. Yes.</p> <p>20 Q. Do you know if it's 50 percent less, 25</p> <p>21 percent less?</p> <p>22 A. It's a lot less.</p> <p>23 Q. How did you determine it was less? What</p> <p>24 methodology did you use?</p>
Page 87	Page 89
<p>1 A. I'm not sure.</p> <p>2 Q. On Page 3 of your report you state that</p> <p>3 Gynemesh PS has been the most studied mesh in pelvic</p> <p>4 reconstructive surgery. Is that an opinion you intend</p> <p>5 to offer in this case?</p> <p>6 A. Yes.</p> <p>7 Q. When you say that it's the most studied mesh</p> <p>8 in pelvic reconstructive surgery, what do you mean by</p> <p>9 that? Do you mean that it's had the most number of</p> <p>10 studies performed or that the -- had the most number</p> <p>11 of patients studied in those studies or both, if that</p> <p>12 makes sense? It's kind of an ineloquent question.</p> <p>13 MR. GAGE: Object to form.</p> <p>14 A. Both, the most studies, the most number of</p> <p>15 patients, the most randomized controlled studies.</p> <p>16 Q. (By Mr. Faes) So what other meshes did you</p> <p>17 compare it to to make that determination that it was</p> <p>18 the most studied --</p> <p>19 A. Well --</p> <p>20 Q. -- in pelvic reconstructive surgery?</p> <p>21 A. The Vypro, the PVDF, Ultrapro. And then</p> <p>22 there's other kits, as well, that are also</p> <p>23 polypropylene mesh, like the Elevate, that have been</p> <p>24 studied quite a bit, as well, but not as much as the</p>	<p>1 A. Well, you can just do a PubMed search.</p> <p>2 Q. Did you keep any documentation of your PubMed</p> <p>3 searches in terms of how many studies for these other</p> <p>4 four meshes?</p> <p>5 A. No, I did not.</p> <p>6 Q. Did you compare the Prolene -- actually, I'm</p> <p>7 going to strike that.</p> <p>8 Different question: Did you do any kind of</p> <p>9 systematic review of the literature on those four</p> <p>10 meshes to determine whether the quality of those</p> <p>11 studies was better or worse than the quality of the</p> <p>12 studies on the Gynemesh PS mesh?</p> <p>13 A. I just did sort of a survey of the studies.</p> <p>14 I didn't go in depth.</p> <p>15 Q. So you'd agree that it wasn't any kind of a</p> <p>16 systematic review?</p> <p>17 A. No.</p> <p>18 Q. Did you compare -- in regards to this</p> <p>19 opinion, that it's the most studied mesh in pelvic</p> <p>20 reconstructive surgery, did you do any comparison to</p> <p>21 the traditional Prolene mesh, see how many studies</p> <p>22 there were where that had been used?</p> <p>23 A. No, I didn't.</p> <p>24 Q. Same question: The IntePro Lite mesh?</p>

23 (Pages 86 to 89)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 90</p> <p>1 A. No.</p> <p>2 Q. What about the Marlex mesh, which is now</p> <p>3 called the Bard mesh?</p> <p>4 A. Uh-huh.</p> <p>5 MR. GAGE: You need to say "yes," not --</p> <p>6 THE WITNESS: No. Yeah. I'm just</p> <p>7 acknowledging that I understood the question. Sorry.</p> <p>8 A. No, I didn't.</p> <p>9 Q. (By Mr. Faes) Would you agree that native</p> <p>10 tissue repair of pelvic organ prolapse is more studied</p> <p>11 than the Gynemesh PS has been in pelvic reconstructive</p> <p>12 surgery?</p> <p>13 A. I am not sure about that. My gut feeling is</p> <p>14 that the Gynemesh is more studied, but I'd have to --</p> <p>15 I'd have to -- I'd have to look at that.</p> <p>16 Q. So -- but it's fair to say, as you sit here</p> <p>17 today --</p> <p>18 A. Uh-huh.</p> <p>19 Q. -- you've never looked at that and you don't</p> <p>20 know, one way or the other, whether native tissue</p> <p>21 repair for repair of pelvic organ prolapse is more</p> <p>22 studied than the Gynemesh PS has been in pelvic</p> <p>23 reconstructive surgery?</p> <p>24 A. I don't know.</p>	<p style="text-align: right;">Page 92</p> <p>1 Q. Is that something you intend to do prior to</p> <p>2 trial?</p> <p>3 A. Perhaps.</p> <p>4 MR. FAES: I would ask counsel, if such</p> <p>5 a demonstrative is ever created, that that be produced</p> <p>6 to us.</p> <p>7 Q. (By Mr. Faes) Do you know how many out of</p> <p>8 those hundred are randomized controlled trials?</p> <p>9 A. I don't have a number off the top of my head.</p> <p>10 Numerous.</p> <p>11 Q. Do you know how many of those studies are</p> <p>12 Gynemesh PS flat mesh by itself?</p> <p>13 A. I don't have a number.</p> <p>14 Q. Do you know if there have been any randomized</p> <p>15 controlled trials of Gynemesh PS flat mesh comparing</p> <p>16 it to comparator device or procedure?</p> <p>17 A. I can't recall right now.</p> <p>18 Q. Do you know if there are any randomized</p> <p>19 controlled trials comparing the Prosima device to an</p> <p>20 alternative device or procedure?</p> <p>21 A. Yes, absolutely.</p> <p>22 Q. How many of those -- how many randomized</p> <p>23 controlled trials do you believe there are that</p> <p>24 compare the Prosima device to a different device</p>
<p style="text-align: right;">Page 91</p> <p>1 Q. You haven't looked at that question?</p> <p>2 A. I haven't looked at that.</p> <p>3 Q. Okay. You also state in your report that</p> <p>4 there are numerous randomized controlled trials and</p> <p>5 over a hundred studies which demonstrate that the</p> <p>6 Gynemesh PS when used by itself or in the Prolift and</p> <p>7 Prosima devices -- I think I said that wrong. Strike</p> <p>8 that and I'll ask a new question.</p> <p>9 You say in your report that there are</p> <p>10 numerous randomized controlled trials and over a</p> <p>11 hundred studies which demonstrate that the Gynemesh PS</p> <p>12 when used by itself or in the Prolift or Prosima</p> <p>13 devices. Is that correct?</p> <p>14 A. That's correct.</p> <p>15 Q. Do you know what the exact number is?</p> <p>16 A. No, I don't.</p> <p>17 Q. Do you have any documentation that you have</p> <p>18 or a list that you intend to refer to at trial as to</p> <p>19 what those greater than a hundred studies are?</p> <p>20 A. None other than my reliance materials.</p> <p>21 Q. But you've never separately broken them out,</p> <p>22 those hundred out of your reliance list for use as</p> <p>23 a demonstrative at trial or anything like that?</p> <p>24 A. No.</p>	<p style="text-align: right;">Page 93</p> <p>1 or procedure?</p> <p>2 A. I believe there's about five or six.</p> <p>3 Q. In the hundred studies that you say</p> <p>4 demonstrate the use of Gynemesh PS, when used by</p> <p>5 itself or in the Prolift or Prosima devices, do you</p> <p>6 know how many of those studies use Gynemesh PS</p> <p>7 abdominally rather than transvaginally?</p> <p>8 A. I don't recall. Not very many.</p> <p>9 Q. In your report you state that there -- you</p> <p>10 don't believe that there is any evidence that the</p> <p>11 Prolene mesh is cytotoxic. Is that correct?</p> <p>12 A. That's correct.</p> <p>13 Q. Is that an opinion you intend to offer in</p> <p>14 this case?</p> <p>15 A. Yes.</p> <p>16 Q. Have you studied what happens to tissue when</p> <p>17 it is exposed to a cytotoxic substance?</p> <p>18 A. I'm sure in biology or in medical school we</p> <p>19 studied, you know, cytotoxicity and what happens to</p> <p>20 tissue in that circumstance.</p> <p>21 Q. As you sit here today, can you tell me what</p> <p>22 the clinical effect would be to tissue if it were</p> <p>23 opposed [sic] to a cytotoxic substance?</p> <p>24 A. Necrosis. Inflammation, necrosis.</p>

24 (Pages 90 to 93)

Christina Pramudji, M.D.

Page 94	Page 96
<p>1 Q. Would you agree that necrotized or -- strike</p> <p>2 that.</p> <p>3 Would you agree that necrotized tissue</p> <p>4 surrounding a mesh could lead to erosion or exposure</p> <p>5 of the mesh?</p> <p>6 A. Yes.</p> <p>7 Q. So isn't one clinical manifestation --</p> <p>8 potential clinical manifestation of -- strike that.</p> <p>9 So if you agree that one potential effect of</p> <p>10 being exposed to a cytotoxic substance is that the</p> <p>11 tissue can undergo necrosis and you agree that</p> <p>12 necrotized tissue surrounding the mesh can lead to an</p> <p>13 erosion or exposure of the mesh, isn't a study that</p> <p>14 shows an erosion or exposure rate of 15 to 20 percent</p> <p>15 evidence that the mesh is, indeed, cytotoxic?</p> <p>16 MR. GAGE: Object to form.</p> <p>17 A. No, not at all. The necrosis around the</p> <p>18 wound can be due to tissue handling, the state of the</p> <p>19 tissue, cautery of the edges, improper sewing</p> <p>20 technique, history of smoking, diabetes, poor blood</p> <p>21 flow. There's just innumerable reasons for necrosis.</p> <p>22 And most of the erosions are right in the suture line,</p> <p>23 so that's a wound healing issue. If it -- if mesh</p> <p>24 were cytotoxic, you would see erosions all over the</p>	<p>1 Q. -- if you want to keep going, I won't cut you</p> <p>2 off. So you've listed multiple potential causes</p> <p>3 of tissue necrosis. We can agree that there are</p> <p>4 multiple potential causes of tissue necrosis.</p> <p>5 Correct?</p> <p>6 A. Yes.</p> <p>7 Q. And we can also agree that one potential</p> <p>8 cause of tissue necrosis is the tissue being exposed</p> <p>9 to a cytotoxic substance. Is that correct?</p> <p>10 A. That's correct.</p> <p>11 Q. On Page 4 of your report you state that</p> <p>12 plaintiffs' experts have said that there are safer or</p> <p>13 better meshes, that these meshes have not been</p> <p>14 demonstrated to be more efficacious based on reliable</p> <p>15 scientific literature like the Gyne -- the Gynemesh</p> <p>16 PS. Is that correct?</p> <p>17 A. That's correct.</p> <p>18 Q. Is that an opinion you tend to offer in this</p> <p>19 case?</p> <p>20 A. Yes.</p> <p>21 Q. Now, specifically, in your report, you</p> <p>22 mention DynaMesh, Vypro and Ultrapro. Is that right?</p> <p>23 A. Correct.</p> <p>24 Q. Are there any other meshes that you have</p>
Page 95	Page 97
<p>1 place and you don't see that. You see them -- the</p> <p>2 vast majority are right in the suture line.</p> <p>3 Q. You don't think a study that shows an erosion</p> <p>4 rate of 15 to 20 percent is an erosion all over the</p> <p>5 place?</p> <p>6 A. No. No. I'm talking about -- I'm talking</p> <p>7 about erosion on the side of the vagina, you know, not</p> <p>8 just in the suture line. If it's in the suture line,</p> <p>9 that's a wound healing problem. If it -- if the mesh</p> <p>10 were cytotoxic, you would see holes on this side of</p> <p>11 the vagina and over here, not just in the incision</p> <p>12 line.</p> <p>13 Q. So is it your testimony that you've never</p> <p>14 seen an erosion any place other than in the incision</p> <p>15 line?</p> <p>16 A. No, I'm not saying that. I'm not saying that</p> <p>17 at all. I have seen that on the sides. Usually an</p> <p>18 arm that was not placed properly through the sulcus,</p> <p>19 but --</p> <p>20 Q. I think you've you've answered my question.</p> <p>21 A. Okay.</p> <p>22 Q. I'm going to move to strike everything after</p> <p>23 that anyway, but --</p> <p>24 A. Okay.</p>	<p>1 studied that you believe have not been demonstrated to</p> <p>2 be more efficacious based on reliable scientific</p> <p>3 literature like the Gynemesh PS?</p> <p>4 A. No.</p> <p>5 MR. GAGE: Just take a quick bathroom</p> <p>6 break.</p> <p>7 MR. FAES: Same here. Let's do it real</p> <p>8 quick.</p> <p>9 THE WITNESS: Yeah.</p> <p>10 (Break.)</p> <p>11 Q. (By Mr. Faes) Dr. Pramudji, we're back on</p> <p>12 the record after a short break. Are you ready to</p> <p>13 proceed?</p> <p>14 A. Yes.</p> <p>15 Q. Before the break we were talking about meshes</p> <p>16 that you believe have not been demonstrated to be</p> <p>17 safer and more efficacious based on the reliable</p> <p>18 scientific literature like Gynemesh PS. Did you study</p> <p>19 the Restorelle mesh?</p> <p>20 A. No, I did not.</p> <p>21 Q. And that's currently your mesh of choice for</p> <p>22 ASC. Correct?</p> <p>23 A. Yes, that's correct.</p> <p>24 Q. Did you study the IntePro mesh?</p>

25 (Pages 94 to 97)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 98</p> <p>1 A. No, I did not.</p> <p>2 Q. Did you study the IntePro Lite mesh?</p> <p>3 A. No.</p> <p>4 Q. Did you study the Elevate mesh?</p> <p>5 A. No.</p> <p>6 Q. What about the Uphold mesh?</p> <p>7 A. No.</p> <p>8 Q. No. Did you know that Ethicon was developing</p> <p>9 a Prosima Plus M device which would have used the</p> <p>10 Ultrapro mesh, rather than the Gynemesh PS mesh just</p> <p>11 like the Prolift Plus M?</p> <p>12 A. Yes, I was aware of that.</p> <p>13 Q. When were you made aware of that?</p> <p>14 A. Pretty early on, because we were -- we were</p> <p>15 asking for it, because we liked the Prolift Plus M</p> <p>16 mesh and we were wondering why the new product was</p> <p>17 made with the Gynemesh PS versus the Prolift Plus M</p> <p>18 mesh.</p> <p>19 Q. Do you anticipate that if the Prosima Plus M</p> <p>20 had been made available with the Ultrapro mesh, do you</p> <p>21 believe that would have become your device of choice</p> <p>22 over the traditional Prosima, just like the Prolift</p> <p>23 Plus M became your device of choice over the Prolift?</p> <p>24 MR. GAGE: Object to form.</p>	<p style="text-align: right;">Page 100</p> <p>1 MR. GAGE: Object to form.</p> <p>2 A. I'm sorry to interrupt. Yes, that's correct.</p> <p>3 Q. (By Mr. Faes) Do you know what the weight in</p> <p>4 grams per meter squared of the Gynemesh PS mesh is?</p> <p>5 A. I can't remember at this moment. I used to</p> <p>6 know. I'd have the look it up.</p> <p>7 Q. On Page 5 you state -- of your report you</p> <p>8 state that the Prosima is minimally invasive compared</p> <p>9 to the abdominal -- abdominal sacrocolpopexy and less</p> <p>10 morbid. Is that an opinion you intend to offer in</p> <p>11 this case?</p> <p>12 A. Yes.</p> <p>13 Q. First of all, let me ask you this: What do</p> <p>14 you mean by less morbid?</p> <p>15 A. Less effect on the body. With the</p> <p>16 sacrocolpopexy, you have more dissection, you have</p> <p>17 more risk of bowel complications compared to Prosima.</p> <p>18 Q. Is there anything else about the ASC</p> <p>19 procedure that you believe is more morbid than the</p> <p>20 Prosima procedure?</p> <p>21 A. It also has a risk of hernia, injury to major</p> <p>22 vessels, bowel obstruction, adhesions.</p> <p>23 Q. Do you believe that the Prosima device</p> <p>24 doesn't carry with it a risk of hernia?</p>
<p style="text-align: right;">Page 99</p> <p>1 A. I'm not sure. I would have to try it out and</p> <p>2 see if I got similar results with it.</p> <p>3 Q. (By Mr. Faes) Do you know why the Prosima</p> <p>4 Plus M device ultimately never came to market?</p> <p>5 A. I don't know why.</p> <p>6 Q. Can you -- well, this is going to be an easy</p> <p>7 question because there's hardly any kits left on</p> <p>8 the market, but can you point to a kit for the</p> <p>9 repair of pelvic organ prolapse which is on the market</p> <p>10 today which uses a mesh that is heavier in weight than</p> <p>11 the Gynemesh PS mesh?</p> <p>12 MR. GAGE: Object to form.</p> <p>13 A. No, I can't.</p> <p>14 Q. (By Mr. Faes) In fact, as you sit here</p> <p>15 today, do you know that all of the mesh kits still on</p> <p>16 the market have mesh that are lighter in weight than</p> <p>17 the Gynemesh PS mesh?</p> <p>18 MR. GAGE: Object to form.</p> <p>19 A. I think they're very similar, maybe slightly</p> <p>20 lighter.</p> <p>21 Q. (By Mr. Faes) But, certainly, none are</p> <p>22 heavier than the --</p> <p>23 A. That's correct.</p> <p>24 Q. -- Gynemesh PS mesh?</p>	<p style="text-align: right;">Page 101</p> <p>1 A. I'm talking about abdominal wall hernia, to</p> <p>2 be clear.</p> <p>3 Q. Okay.</p> <p>4 A. So because of the trocars or the incision for</p> <p>5 an abdominal sacrocolpopexy, there's going to be a</p> <p>6 risk of abdominal wall hernia.</p> <p>7 Q. And is that a risk that -- is that not a risk</p> <p>8 of the Prosima device in your opinion?</p> <p>9 A. Right, because there's no abdominal wall</p> <p>10 incision for a Prosima.</p> <p>11 Q. Can -- is -- can the Prosima device cause</p> <p>12 other hernias, such as an inguinal hernia.</p> <p>13 A. No, it cannot cause that.</p> <p>14 Q. Do you believe the Prosima device doesn't</p> <p>15 have a risk of bowel injury?</p> <p>16 A. It's a very small risk. If you have apical</p> <p>17 dissection into an enterocele, it could happen. Or if</p> <p>18 you're doing a posterior Prosima, you have a risk of</p> <p>19 rectal injury, but it's a very small risk.</p> <p>20 Q. Do you believe it's a --</p> <p>21 A. And it's --</p> <p>22 Q. -- smaller risk than the risk of bowel injury</p> <p>23 with the ASC?</p> <p>24 A. Yes, much smaller risk.</p>

26 (Pages 98 to 101)

Christina Pramudji, M.D.

Page 102	Page 104
<p>1 Q. Now, you state that the Prosima device is</p> <p>2 less invasive. Would you agree that a doctor or</p> <p>3 patient might choose a more invasive surgery to avoid</p> <p>4 potentially life complications of a less invasive</p> <p>5 device or procedure?</p> <p>6 A. What are "life complications"?</p> <p>7 Q. Did I say life com -- I meant life-changing</p> <p>8 complications.</p> <p>9 A. Oh, okay.</p> <p>10 Q. So let me -- did -- is that not what I said?</p> <p>11 MR. GAGE: Yeah, I'm going to -- if</p> <p>12 you're going to rephrase -- if you'll withdraw and</p> <p>13 rephrase the question.</p> <p>14 MR. FAES: Yeah, I'll withdraw it and</p> <p>15 rephrase it.</p> <p>16 MR. GAGE: Thank you.</p> <p>17 Q. (By Mr. Faes) Would you agree that a doctor</p> <p>18 or patient might choose a more invasive surgery to</p> <p>19 avoid potentially life-changing complications of a</p> <p>20 less invasive device or procedure?</p> <p>21 A. Yes, I agree with that statement.</p> <p>22 Q. Would you agree that a doctor and patient</p> <p>23 should know about all of the potentially life-changing</p> <p>24 complications of the device or the procedure, so they</p>	<p>1 placed?</p> <p>2 A. I can agree with that, although I would say</p> <p>3 that I've never seen that or heard of it, but</p> <p>4 hypothetically, that -- I would agree with that</p> <p>5 statement.</p> <p>6 Q. You've never seen or heard of a vaginal</p> <p>7 support device that needed to be removed prior to the</p> <p>8 21 days elapsing because of an apparent infection?</p> <p>9 A. No.</p> <p>10 Q. That's not cited on Page 41 of your report in</p> <p>11 an article?</p> <p>12 A. Oh, I was talking about my own experience.</p> <p>13 Sorry.</p> <p>14 Q. Oh, okay.</p> <p>15 A. Yeah.</p> <p>16 Q. Okay. So you're aware that that --</p> <p>17 A. Yes.</p> <p>18 Q. -- that can occur?</p> <p>19 A. Yes.</p> <p>20 Q. Now, you've testified before that you're</p> <p>21 familiar with the ProteGen project -- ProteGen</p> <p>22 product. Correct?</p> <p>23 A. Correct.</p> <p>24 Q. And you testified that you know that the</p>
Page 103	Page 105
<p>1 can make an informed choice about what device or</p> <p>2 procedure they would like to have performed on them?</p> <p>3 A. I think a doctor and their patient need to</p> <p>4 know about potential complications that can occur with</p> <p>5 any surgery that they're going to have, knowing</p> <p>6 realistically that you may not be able to anticipate</p> <p>7 rare complications.</p> <p>8 Q. But even if a complication is rare, you would</p> <p>9 -- if it's potentially life-changing or devastating,</p> <p>10 you would agree that it's important for both the</p> <p>11 doctor and patient to know about that, in order to</p> <p>12 make an informed choice about whether they want to</p> <p>13 proceed with that surgery?</p> <p>14 A. Yes, that's fair.</p> <p>15 Q. Would you agree that if a -- even if a</p> <p>16 Prosima device is placed correctly by a surgeon, the</p> <p>17 vaginal support device can fall out on its own before</p> <p>18 the 21-day prescribed healing period has lapsed?</p> <p>19 A. That can happen, yes, depending on how their</p> <p>20 body handles the micral suture.</p> <p>21 Q. Would you agree that if an infection occurs</p> <p>22 around the vaginal support device, removal of that</p> <p>23 vaginal support device is indicated and necessary even</p> <p>24 if the prescribed 21 days had not passed since it was</p>	<p>1 ProteGen was removed from the market because the</p> <p>2 erosion rates were unacceptably high?</p> <p>3 A. That's correct.</p> <p>4 Q. Do you know what the reported rates of</p> <p>5 erosion were for the ProteGen?</p> <p>6 A. I can't recall right now.</p> <p>7 Q. How high would the erosion and exposure rates</p> <p>8 for the Prosima need to be in order for you to say the</p> <p>9 erosion rate was unacceptably high?</p> <p>10 A. I think I would feel uncomfortable if I were</p> <p>11 seeing an erosion rate upwards of 30 percent.</p> <p>12 Q. So if the erosion rate for the Prosima were</p> <p>13 25 percent, you wouldn't say that that was</p> <p>14 unacceptably high?</p> <p>15 A. No.</p> <p>16 Q. One in four patients had an erosion or</p> <p>17 exposure?</p> <p>18 A. I would -- I would think twice about it and</p> <p>19 it would depend on how bad the erosions were and what</p> <p>20 kind of treatment they needed and who -- who they are,</p> <p>21 because as you know from the literature a lot of</p> <p>22 patients can live their -- with an erosion, a small</p> <p>23 erosion. So there's a few factors to take into</p> <p>24 consideration. That's kind of a gray area. You have</p>

27 (Pages 102 to 105)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 106</p> <p>1 to take everything into consideration.</p> <p>2 Q. But anything 30 percent or higher --</p> <p>3 A. Yeah.</p> <p>4 Q. -- with the Prosima you would find</p> <p>5 unacceptably high?</p> <p>6 A. I think, if I had one in three, that would --</p> <p>7 that would be a little bit high.</p> <p>8 Q. Is your answer the same for the Prolift</p> <p>9 device?</p> <p>10 A. Yes.</p> <p>11 Q. Is it the same for the Gynemesh PS flat mesh?</p> <p>12 A. Yes.</p> <p>13 Q. Do you intend to offer an opinion in this</p> <p>14 case as to whether the warnings in the Prosima IFU</p> <p>15 were sufficient to apprise doctors of the risks of</p> <p>16 this product?</p> <p>17 A. Yes, I believe they were sufficient.</p> <p>18 Q. Do you know what the standards were that</p> <p>19 Ethicon applied in terms of what needed to be included</p> <p>20 in the warnings about the Prosima?</p> <p>21 A. Yes.</p> <p>22 Q. And what standards do you believe Ethicon</p> <p>23 applied regarding what needed to be included in the</p> <p>24 warnings about Prosima?</p>	<p style="text-align: right;">Page 108</p> <p>1 just read it for the first time?</p> <p>2 A. That's correct.</p> <p>3 Q. If something in the IFU changes, is there any</p> <p>4 way that you would know if the information in the IFU</p> <p>5 had changed?</p> <p>6 A. Not unless someone told me about it.</p> <p>7 Q. In all your years implanting products for --</p> <p>8 strike that.</p> <p>9 In all of your years of implanting products</p> <p>10 manufactured by Ethicon, has any Ethicon</p> <p>11 representative or sales rep or anybody whoever -- who</p> <p>12 works for Ethicon ever came to you and told you that</p> <p>13 the IFU for a product had been updated?</p> <p>14 A. Not that I can recall.</p> <p>15 Q. Do you know if the Prosima IFU was ever</p> <p>16 updated?</p> <p>17 A. I'm not sure about that one.</p> <p>18 Q. Do you know if the Gynemesh PS IFU was ever</p> <p>19 updated?</p> <p>20 A. I can't recall.</p> <p>21 Q. Do you know if the Gynemesh PS IFU was</p> <p>22 updated this year?</p> <p>23 A. Not that I can recall right now.</p> <p>24 Q. When you read an IFU, do you assume that the</p>
<p style="text-align: right;">Page 107</p> <p>1 A. I think they were -- you know -- excuse me --</p> <p>2 complications that had a certain degree of frequency</p> <p>3 and severity and anything that could potentially be</p> <p>4 life changing that they would try to include.</p> <p>5 Q. I apologize if you've been asked these next</p> <p>6 couple questions before, but you've been deposed,</p> <p>7 what, five times and I can't remember everything you</p> <p>8 said.</p> <p>9 MR. GAGE: Perfect. Perfect.</p> <p>10 Q. (By Mr. Faes) Have you ever in your career</p> <p>11 been involved in writing or preparing writings for a</p> <p>12 medical device?</p> <p>13 A. No.</p> <p>14 Q. That's wrong in my outline. Have you ever</p> <p>15 been in your career involved in writing or preparing</p> <p>16 IFUs for a medical device?</p> <p>17 MR. GAGE: Object to form.</p> <p>18 A. No, I have not.</p> <p>19 Q. (By Mr. Faes) In your practice, do you</p> <p>20 typically read the IFU for each mesh kit or device</p> <p>21 that you use before using it?</p> <p>22 A. Yes, I do.</p> <p>23 Q. You don't read -- do you -- you don't read</p> <p>24 the IFU every time you use the device. Correct? You</p>	<p style="text-align: right;">Page 109</p> <p>1 IFU is disclosing to you each of the risks and</p> <p>2 complications the company knew could occur with the</p> <p>3 kit or device that you're using?</p> <p>4 A. No, because I also take into consideration my</p> <p>5 surgical training and I know that there's some risks</p> <p>6 of surgery that aren't going to be -- aren't going to</p> <p>7 be included there, so I don't rely on the IFU to tell</p> <p>8 me all the risks.</p> <p>9 Q. Do you assume that when you read an IFU from</p> <p>10 a company regarding a mesh kit or medical device that</p> <p>11 the company is disclosing to you those complications</p> <p>12 and risks that could be significant for the patient</p> <p>13 and known to the company?</p> <p>14 A. Again, not necessarily because there's some</p> <p>15 that you just apply your surgical training to and you</p> <p>16 take that into consideration and assume that those are</p> <p>17 going to be some of the risks.</p> <p>18 Q. Do you assume that when you read an IFU for a</p> <p>19 medical device that the company was disclosing any</p> <p>20 risks and complications that would be inherent to the</p> <p>21 mesh material, so that you would know what those risks</p> <p>22 are?</p> <p>23 A. Yes, I would assume that they would -- they</p> <p>24 would include -- include those sorts of things</p>

Christina Pramudji, M.D.

Page 110	Page 112
<p>1 specific to the device.</p> <p>2 Q. Do you know whether or not -- strike that.</p> <p>3 Do you know whether or not one of the</p> <p>4 purposes of the IFU is to disclose each of the risks</p> <p>5 and complications that can occur with the use of that</p> <p>6 mesh kit in a woman's body?</p> <p>7 MR. GAGE: Object to form.</p> <p>8 A. I think it's to -- to communicate the risks,</p> <p>9 but it's not meant to be comprehensive and I don't</p> <p>10 think surgeons take it to be comprehensive either.</p> <p>11 Q. (By Mr. Faes) As you sit here today, do you</p> <p>12 have an understanding of any standard whatsoever as to</p> <p>13 what risks and complications are supposed to be</p> <p>14 disclosed in an IFU?</p> <p>15 A. I believe there are some guidelines from the</p> <p>16 FDA that help guide companies in what they should put</p> <p>17 into the IFU.</p> <p>18 Q. Do you know what those guidelines are called?</p> <p>19 A. No, I don't know what they're called.</p> <p>20 Q. Do you know if you've reviewed those</p> <p>21 guidelines before?</p> <p>22 A. I have seen them before, yes.</p> <p>23 Q. Would you agree that your background and</p> <p>24 experience is not necessarily the same as other</p>	<p>1 A. I think it would depend on what -- you</p> <p>2 know -- what you're talking about, what sort of</p> <p>3 situation you're talking about.</p> <p>4 Q. So you'd agree that it's possible that a --</p> <p>5 there could be a situation where a physician wouldn't</p> <p>6 know about a potential risk or complication of the</p> <p>7 Prosima or Prolift that you did know about and that</p> <p>8 doctor could still be a reasonable and prudent</p> <p>9 physician and be doing his work within the standard of</p> <p>10 care?</p> <p>11 MR. GAGE: Object to form.</p> <p>12 A. I think people have, you know, different</p> <p>13 training in their residency, different experience, so</p> <p>14 it's possible, but I think it's unlikely, because I</p> <p>15 think any reasonable pelvic surgeon would be able to</p> <p>16 anticipate the potential complications of pelvic --</p> <p>17 any pelvic surgery, whether it's with a kit or native</p> <p>18 tissue or whatever technique that you're using.</p> <p>19 Q. (By Mr. Faes) So is --</p> <p>20 A. I don't think you would be surprised by</p> <p>21 pelvic pain or be surprised by poor wound healing.</p> <p>22 That should be anticipated.</p> <p>23 Q. So is it your testimony that if there was a</p> <p>24 risk or complication of the Prosima or Prolift device</p>
Page 111	Page 113
<p>1 doctors who use medical devices or might consider</p> <p>2 using the Prosima?</p> <p>3 MR. GAGE: Object to form.</p> <p>4 A. Well, of course, there's going to be a wide</p> <p>5 range of doctors that might use medical devices.</p> <p>6 There's going to be some that are very -- more</p> <p>7 experienced than others.</p> <p>8 Q. (By Mr. Faes) You'd agree that you might</p> <p>9 know about a complication from a particular mesh</p> <p>10 device or kit from your own experience that another</p> <p>11 doctor might not know about?</p> <p>12 A. I don't know if I would agree with that. I</p> <p>13 think that if you're a pelvic surgeon, if you're --</p> <p>14 you're doing operations and you've been through</p> <p>15 residency, then you would be aware of the potential</p> <p>16 complications. You may not have experienced it. The</p> <p>17 more surgery you do, the more you're bound to have</p> <p>18 complications along the way, but you would be aware of</p> <p>19 it.</p> <p>20 Q. So if you knew about a potential risk or</p> <p>21 complication from the Prosima or Prolift device that</p> <p>22 another physician didn't know about, would you</p> <p>23 consider that physician to not be a diligent and</p> <p>24 reasonable physician for not knowing about that?</p>	<p>1 that a physician didn't know about, that that</p> <p>2 physician wasn't reasonable and prudent, using your</p> <p>3 words?</p> <p>4 A. I don't think I used those words, but. . .</p> <p>5 Q. I think you said reasonable, so let me --</p> <p>6 A. Okay.</p> <p>7 Q. -- let me strike that and I'll ask it again.</p> <p>8 A. Okay.</p> <p>9 Q. So is it your testimony that if there is a</p> <p>10 risk or complication of the Prosima or Prolift device</p> <p>11 that an implanting physician didn't know about, that</p> <p>12 that physician wasn't reasonable in his treatment and</p> <p>13 care?</p> <p>14 MR. GAGE: Object to form.</p> <p>15 A. I would have to say that they're missing --</p> <p>16 they may be missing some knowledge or experience.</p> <p>17 Q. (By Mr. Faes) Yeah. My question is actually</p> <p>18 a little different than that.</p> <p>19 A. Okay.</p> <p>20 Q. My question isn't whether their -- whether</p> <p>21 they're missing knowledge and experience. My question</p> <p>22 is whether you consider them to not be reasonable in</p> <p>23 their treatment and care of a physician -- of a</p> <p>24 patient if there was a risk or complication of the</p>

29 (Pages 110 to 113)

Christina Pramudji, M.D.

Page 114	Page 116
<p>1 Prosima or Prolift device that they didn't know about.</p> <p>2 MR. GAGE: Object to form.</p> <p>3 A. No, I disagree because they could still be</p> <p>4 reasonable, they could still be giving the patient</p> <p>5 good treatment and care even if they didn't know about</p> <p>6 that risk or complication.</p> <p>7 Q. (By Mr. Faes) In doing your work on this</p> <p>8 case, have you ever been curious as to what the</p> <p>9 regulatory affairs professionals department in</p> <p>10 Ethicon, the professionals who are required to make</p> <p>11 sure an IFU complies with FDA regulations, are you --</p> <p>12 have you been curious about what they thought needed</p> <p>13 to be in an IFU?</p> <p>14 MR. GAGE: Object to form.</p> <p>15 A. Not really.</p> <p>16 Q. (By Mr. Faes) That's not something that you</p> <p>17 thought would be helpful in forming your opinions in</p> <p>18 this case, that the Prosima and Prolift and Gynemesh</p> <p>19 PS IFUs are adequate?</p> <p>20 A. No, because I think they're adequate. I</p> <p>21 think that they did adequately warn about potential</p> <p>22 complications, so I think they did a fine job putting</p> <p>23 it together.</p> <p>24 Q. Would you agree with me that if Ethicon</p>	<p>1 and start over.</p> <p>2 Do you agree that mesh shrinkage or</p> <p>3 contraction can lead to severe pelvic pain?</p> <p>4 A. No.</p> <p>5 Q. Do you believe that wound contraction can</p> <p>6 cause -- strike that.</p> <p>7 Do you agree that wound contraction or scar</p> <p>8 contraction around a mesh can lead to severe pelvic</p> <p>9 pain?</p> <p>10 A. Yes.</p> <p>11 Q. Do you agree that -- strike that.</p> <p>12 Do you agree that wound contraction or scar</p> <p>13 contraction surrounding mesh can lead to painful</p> <p>14 sexual intercourse?</p> <p>15 A. (No response.)</p> <p>16 Q. Do you want me to restate it since you can't</p> <p>17 read it?</p> <p>18 MR. GAGE: It's hard to read on the</p> <p>19 screen here.</p> <p>20 MR. FAES: Yeah.</p> <p>21 A. Please.</p> <p>22 Q. (By Mr. Faes) Do you agree that wound</p> <p>23 contraction or scar contraction surrounding the mesh</p> <p>24 can lead to painful sexual intercourse?</p>
Page 115	Page 117
<p>1 medical affairs knew that there was a potential risk</p> <p>2 or complication attributable to the Gynemesh PS mesh,</p> <p>3 itself, which, if occurred, could cause severe</p> <p>4 permanent injury to a woman, that risk should be</p> <p>5 disclosed in the IFU? Would you agree with that</p> <p>6 statement?</p> <p>7 A. No, because they're going to have multiple</p> <p>8 discussions and opinions and bouncing things back and</p> <p>9 forth and I think that what they put in the IFU is</p> <p>10 perfectly adequate and reliable.</p> <p>11 Q. Have you ever studied the question of what</p> <p>12 risks and complications were known to doctors across</p> <p>13 the country with various backgrounds and levels of</p> <p>14 experience with regard to the use of the Prosima?</p> <p>15 A. No, I have not studied that.</p> <p>16 Q. Same question: Gynemesh PS?</p> <p>17 A. No.</p> <p>18 Q. Same question: Prolift?</p> <p>19 A. No.</p> <p>20 Q. Same question: Prolift Plus M?</p> <p>21 A. No.</p> <p>22 Q. I know you're not giving an opinion on,</p> <p>23 but . . . Do you agree that -- well, actually, I think</p> <p>24 I know your answer to this. I'm going to strike that</p>	<p>1 A. Yes. And it can also occur with wound</p> <p>2 contraction without mesh. It occurs in native tissue</p> <p>3 repairs, as well.</p> <p>4 MR. FAES: Object and move to strike</p> <p>5 after the answer "yes."</p> <p>6 Q. (By Mr. Faes) Same question: Inability to</p> <p>7 -- with regard to inability to engage in sexual</p> <p>8 intercourse?</p> <p>9 MR. GAGE: Object to form.</p> <p>10 Q. (By Mr. Faes) Since he's going to object to</p> <p>11 the form, I'll withdraw that and ask the whole</p> <p>12 question. Would you agree that wound contraction or</p> <p>13 scar contraction surrounding the mesh can lead to</p> <p>14 inability to engage in sexual intercourse?</p> <p>15 A. I don't think that there would be a case</p> <p>16 where that would -- would occur, where they would be</p> <p>17 unable to engage in sexual intercourse.</p> <p>18 Q. But you did agree that it can cause painful</p> <p>19 sexual intercourse?</p> <p>20 A. Yes, pelvic -- pelvic surgery scarring can</p> <p>21 cause painful intercourse.</p> <p>22 Q. Would you agree that intercourse can be so</p> <p>23 painful to where a person is unable to engage in</p> <p>24 sexual intercourse?</p>

30 (Pages 114 to 117)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 118</p> <p>1 A. Uninterested, unwilling, but not unable.</p> <p>2 It's not as if the vagina is completely closed, but if</p> <p>3 it's -- if you're saying because of pain, then, yes,</p> <p>4 where they would be un -- unwilling, uninterested.</p> <p>5 Physically, they would be able to have intercourse,</p> <p>6 but it would be too painful.</p> <p>7 Q. So you make a distinction between someone who</p> <p>8 is unable to have sexual intercourse because it's too</p> <p>9 painful versus someone who is just physically unable</p> <p>10 to have intercourse?</p> <p>11 A. Well, yes. I mean, there are -- especially</p> <p>12 with native tissue repairs, there are situations where</p> <p>13 the vagina is so scared and contracted where they are</p> <p>14 physically unable to have intercourse, not just</p> <p>15 because of pain, because they -- their vagina is</p> <p>16 absolutely too small.</p> <p>17 Q. Okay. So you're --</p> <p>18 A. And I don't --</p> <p>19 Q. -- you're making a distinction, not to be</p> <p>20 indelicate, but between someone who is physically</p> <p>21 unable to be penetrated and someone who --</p> <p>22 A. Has --</p> <p>23 Q. -- prefers not to be because it's too</p> <p>24 painful.</p>	<p style="text-align: right;">Page 120</p> <p>1 A. Yes, as in all pelvic surgery.</p> <p>2 Q. Would you agree that one of the risks of the</p> <p>3 pelvic organ prolapse products is that they can lead</p> <p>4 to dyspareunia?</p> <p>5 A. Yes, as in all pelvic surgery.</p> <p>6 MR. FAES: Move to strike after the</p> <p>7 answer "yes."</p> <p>8 Q. (By Mr. Faes) Would you agree that one of</p> <p>9 the risks of the pelvic organ prolapse products is</p> <p>10 that they can lead to multiple surgical interventions</p> <p>11 to treat the complications?</p> <p>12 A. Yes, that can occur.</p> <p>13 Q. Would you agree that one of the risks of the</p> <p>14 pelvic organ prolapse products is that a woman can</p> <p>15 sustain life-changing complications as a result of</p> <p>16 those products?</p> <p>17 A. Yes, that can occur.</p> <p>18 Q. Would you agree that one of the risks of the</p> <p>19 pelvic organ prolapse products is erosions at multiple</p> <p>20 sites?</p> <p>21 A. Yes.</p> <p>22 Q. Would you agree that with the pelvic organ</p> <p>23 prolapse products, most women who have erosions or</p> <p>24 extrusions require surgical intervention?</p>
<p style="text-align: right;">Page 119</p> <p>1 A. Right.</p> <p>2 Q. Is that right?</p> <p>3 A. Yes.</p> <p>4 Q. Would you agree that one of the risks of the</p> <p>5 -- I'm going to strike that and ask if we can agree</p> <p>6 to something, so I don't have to re-ask these</p> <p>7 questions three different times. For the purposes</p> <p>8 of these questions, as we discussed earlier, when</p> <p>9 I refer to the pelvic organ prolapse products,</p> <p>10 I'm referring to the Prolift, the Prosima and the</p> <p>11 Gynemesh PS, which are the three products that you're</p> <p>12 offering an opinion on. If you can't answer the</p> <p>13 question the same way for all three products, let me</p> <p>14 know and then I'll have to go through each three</p> <p>15 separately. Can we agree to that?</p> <p>16 A. Yes.</p> <p>17 Q. Would you agree that one of the risks of the</p> <p>18 pelvic organ prolapse products is that they can lead</p> <p>19 to complex mesh erosions?</p> <p>20 MR. GAGE: Object to form.</p> <p>21 A. Yes, that is a risk.</p> <p>22 Q. (By Mr. Faes) Would you agree that one of</p> <p>23 the risks with the pelvic organ prolapse products is</p> <p>24 that they can lead to chronic pain syndrome?</p>	<p style="text-align: right;">Page 121</p> <p>1 A. Yes.</p> <p>2 Q. Would you agree that with the Pros -- or</p> <p>3 strike that.</p> <p>4 Would you agree that with the pelvic organ</p> <p>5 prolapse products multiple attempts to excise the mesh</p> <p>6 may be required?</p> <p>7 A. Yes.</p> <p>8 Q. Would you agree with the pelvic organ</p> <p>9 prolapse that one of the risks is life-changing</p> <p>10 complications?</p> <p>11 MR. GAGE: Object to form.</p> <p>12 A. Yes.</p> <p>13 Q. (By Mr. Faes) Would you agree that one of</p> <p>14 the risks of the pelvic organ prolapse products is</p> <p>15 incapacitating pelvic pain?</p> <p>16 A. Yes, as in all pelvic surgery.</p> <p>17 MR. FAES: Move to strike after the</p> <p>18 answer "yes."</p> <p>19 Q. (By Mr. Faes) Would you agree that one of</p> <p>20 the risks of the pelvic organ prolapse products is</p> <p>21 large scale erosions that are not easy to resolve?</p> <p>22 A. There's a very remote risk.</p> <p>23 Q. But is the answer yes?</p> <p>24 A. Yes.</p>

Christina Pramudji, M.D.

<p style="text-align: right;">Page 122</p> <p>1 Q. It is risk. The list of complications and</p> <p>2 risks that I just asked you about, do you know whether</p> <p>3 or not Ethicon knew about all those risks on the day</p> <p>4 the pelvic organ prolapse products first went on the</p> <p>5 market?</p> <p>6 A. I can't recall.</p> <p>7 Q. So you don't know, one way or the other,</p> <p>8 sitting here today?</p> <p>9 A. I don't -- yes, I don't know.</p> <p>10 Q. If they did know, do you agree that those</p> <p>11 risks should have been in the IFU?</p> <p>12 A. I think those are risks that pelvic surgeons</p> <p>13 would anticipate, because as I stated, most of those</p> <p>14 risks, with the exception of the erosion, are risks of</p> <p>15 pelvic surgery.</p> <p>16 Q. Okay. I didn't ask about whether they were</p> <p>17 risks that pelvic surgeons would anticipate. My</p> <p>18 question was very specific. My question was: If</p> <p>19 Ethicon did know about those risks, do you agree that</p> <p>20 those risks should have been put in the IFU?</p> <p>21 MR. GAGE: Object to form.</p> <p>22 A. I don't think they needed to be in the IFU,</p> <p>23 because the surgeons with their knowledge and being</p> <p>24 professionals would be able to anticipate that.</p>	<p style="text-align: right;">Page 124</p> <p>1 MR. FAES: Yeah, I think -- yeah, yeah,</p> <p>2 yeah, yeah. That's fine.</p> <p>3 MR. GAGE: Because you might be entitled</p> <p>4 to a few more minutes. I don't know.</p> <p>5 MR. FAES: Yeah, I think ten.</p> <p>6 Anyway. . .</p> <p>7 Q. (By Mr. Faes) Would you agree with the way</p> <p>8 -- strike that.</p> <p>9 Would you agree that compared to the way the</p> <p>10 mesh was used before the Prolift, the Prolift provided</p> <p>11 for more mesh to be put in a woman's pelvis than had</p> <p>12 been previously used?</p> <p>13 MR. GAGE: Object to form.</p> <p>14 A. I think it depended on how that surgeon was</p> <p>15 configuring the Gynemesh supplementation, so it could</p> <p>16 be the same, it could be more, it could be less.</p> <p>17 Q. (By Mr. Faes) Do you believe that there is a</p> <p>18 sheet of Gynemesh PS flat mesh available as a single</p> <p>19 sheet that is more area than the mesh in the entire</p> <p>20 Prolift kit?</p> <p>21 A. Oh, in the Total Prolift?</p> <p>22 Q. Yes.</p> <p>23 A. No. I think the Total Prolift is probably</p> <p>24 more. I'm thinking about one compartment at a time.</p>
<p style="text-align: right;">Page 123</p> <p>1 MR. FAES: Move to strike after the word</p> <p>2 "IFU."</p> <p>3 Q. (By Mr. Faes) And that's your opinion for</p> <p>4 all of the risks that we just went through today?</p> <p>5 A. Yes.</p> <p>6 Q. When the Prosima first came onto the market,</p> <p>7 surgeons were not experienced on any long-term basis</p> <p>8 with implanting mesh with a vaginal support device.</p> <p>9 Correct?</p> <p>10 A. That's correct.</p> <p>11 Q. Do you know the area of the -- do you know</p> <p>12 the square area of the mesh used in the Prosima kits?</p> <p>13 A. Not off the top of my head, no.</p> <p>14 MR. GAGE: Object. Form.</p> <p>15 Q. (By Mr. Faes) And I think you've already</p> <p>16 answered this question: You don't know what sizes and</p> <p>17 configurations the Gynemesh PS mesh is offered in.</p> <p>18 Correct?</p> <p>19 A. That's correct.</p> <p>20 MR. GAGE: I show about eight minutes</p> <p>21 before she needs to go.</p> <p>22 MR. FAES: Okay.</p> <p>23 MR. GAGE: And we can sort out at 4:20</p> <p>24 how much -- did you get three hours in, did you not.</p>	<p style="text-align: right;">Page 125</p> <p>1 I think if you combine -- you -- you know -- combined</p> <p>2 an anterior and posterior Gynemesh, it would probably</p> <p>3 be more than a Prolift, Total Prolift.</p> <p>4 Q. Okay. What about just one Prolift, just the</p> <p>5 anterior or just the posterior, do you believe that</p> <p>6 there's a sheet of Gynemesh PS that's available that</p> <p>7 would be more mesh, in terms of total square area than</p> <p>8 either the anterior Prolift with the arms included or</p> <p>9 the posterior Prolift with the arms included?</p> <p>10 A. Yeah. I think it would probably be very</p> <p>11 similar once you added it together. And whenever you</p> <p>12 do a Prolift, you usually trim a lot of the mesh --</p> <p>13 Q. What --</p> <p>14 A. -- on the tail or on the sides.</p> <p>15 Q. What size Gynemesh PS would that be that</p> <p>16 would greater than the Prolift?</p> <p>17 A. I mean, I think one size was, I think, ten by</p> <p>18 ten centimeters, if I remember correctly. And so it</p> <p>19 just depends on how the surgeon fashioned it. So it</p> <p>20 could be more, it could be less.</p> <p>21 Q. Do you know if there's more mesh in an</p> <p>22 anterior or posterior Prolift than what would be</p> <p>23 contained in a ten by ten centimeter strip of Gynemesh</p> <p>24 PS?</p>

32 (Pages 122 to 125)

Christina Pramudji, M.D.

Page 126	Page 128
<p>1 A. It's less, the anterior Prolift? The</p> <p>2 anterior Prolift is bigger than a posterior, yeah.</p> <p>3 Q. What do you believe the area of the posterior</p> <p>4 Prolift is?</p> <p>5 A. I don't know off the top of my head. I mean,</p> <p>6 I'm just picturing it from having used it. It's not</p> <p>7 ten by ten centimeters.</p> <p>8 Q. So you don't --</p> <p>9 A. It's much less than that, even if you add the</p> <p>10 arms.</p> <p>11 Q. You don't know the total area with the arms,</p> <p>12 but you -- but you believe it's less than ten by ten</p> <p>13 centimeters?</p> <p>14 A. Absolutely.</p> <p>15 Q. You believe it's less than a hundred square</p> <p>16 centimeters?</p> <p>17 A. Absolutely.</p> <p>18 Q. Is the same -- is the answer --</p> <p>19 A. Because you trim it. You don't use the whole</p> <p>20 thing. And you trim the arms.</p> <p>21 Q. Do you know if when physicians use a</p> <p>22 ten-by-ten sheet of Gynemesh PS, whether or not they</p> <p>23 typically trim it or typically use the entire square</p> <p>24 of mesh?</p>	<p>1 depended on how that surgeon used the Gynemesh. So if</p> <p>2 they're using a Total Prolift, they would have</p> <p>3 potentially used two Gynemesh grafts on that same</p> <p>4 woman previously, so it could still be the same, more</p> <p>5 or less, depending on how they cut their Gynemesh and</p> <p>6 how they utilize it.</p> <p>7 Q. Okay. Let me ask you this question --</p> <p>8 A. Okay.</p> <p>9 Q. -- would you agree that compared with the way</p> <p>10 mesh was used for the repair of pelvic organ prolapse</p> <p>11 before the transvaginal mesh technique with the</p> <p>12 Gynemesh Prolene Soft, the Prolene Soft provided for</p> <p>13 more mesh -- strike that.</p> <p>14 Would you agree with me that compared with</p> <p>15 the way mesh was used for the repair of pelvic organ</p> <p>16 prolapse before the transvaginal mesh technique using</p> <p>17 the Gynemesh Prolene Soft was developed, the</p> <p>18 transvaginal technique with Gynemesh Prolene Soft</p> <p>19 provided for more mesh to be put in a woman's pelvis</p> <p>20 than had been previously used for pelvic organ</p> <p>21 prolapse repair?</p> <p>22 MR. GAGE: Object to form.</p> <p>23 A. I can't really answer that, because there was</p> <p>24 no standardized way to do that surgery before.</p>
Page 127	Page 129
<p>1 A. They typically trim it. That's what I said</p> <p>2 earlier, it could be the same, it could be more, it</p> <p>3 could be less.</p> <p>4 Q. So you disagree that, compared with the way</p> <p>5 the mesh was typically used before the Prolift, the</p> <p>6 Prolift provides for more mesh to be put in a woman's</p> <p>7 pelvis than had been previously used before Prolift</p> <p>8 kits were available?</p> <p>9 MR. GAGE: Object to form.</p> <p>10 A. Correct, I disagree with that.</p> <p>11 Q. (By Mr. Faes) But only with -- only if just</p> <p>12 the anterior or posterior is used by itself?</p> <p>13 A. Well, if -- okay. If you -- yeah, comparing</p> <p>14 one compartment to one Gynemesh graft, yeah, comparing</p> <p>15 one. But if you did a Gynemesh graft in each</p> <p>16 compartment --</p> <p>17 Q. Right. So --</p> <p>18 A. -- that would be the comparison. I wouldn't</p> <p>19 compare one Gynemesh graft to a Total Prolift.</p> <p>20 Q. So would you agree that, compared to the way</p> <p>21 the mesh was used before the Total Prolift, the Total</p> <p>22 Prolift provided for more mesh to be put in a woman's</p> <p>23 pelvis than had generally previously been used?</p> <p>24 A. I feel like we're going in circles. It just</p>	<p>1 Q. (By Mr. Faes) So is the answer to my</p> <p>2 question you can't -- you can't answer one way or</p> <p>3 another, you just don't know?</p> <p>4 A. It's a question that cannot be answered</p> <p>5 because it was not a standardized technique.</p> <p>6 Q. If Ethicon medical affairs believed that a</p> <p>7 caution needed to be taken by a doctor before using</p> <p>8 Prosima in a particular class of women, should that</p> <p>9 have been put in the IFU?</p> <p>10 A. I would say yes to that.</p> <p>11 Q. If Ethicon -- I think I'll ask two more</p> <p>12 questions and then you probably gotta get out of here.</p> <p>13 Right? Okay. Unless you need to get out of here</p> <p>14 right now. Two more questions --</p> <p>15 MR. GAGE: The real clock is faster than</p> <p>16 my watch yes.</p> <p>17 MR. FAES: Okay.</p> <p>18 MR. GAGE: Yeah.</p> <p>19 Q. (By Mr. Faes) If Ethicon medical affairs</p> <p>20 believed that a caution should be used before putting</p> <p>21 a Prosima into a woman based on some fact about her</p> <p>22 demographics or her age or her level of prolapse or</p> <p>23 comorbidities or anything that was specific that could</p> <p>24 be related to specific patients, should that</p>

Christina Pramudji, M.D.

Page 130	Page 132
<p>1 information have been in the IFU, so that doctors</p> <p>2 would have that information when deciding to do with</p> <p>3 their patients?</p> <p>4 MR. GAGE: Object to form.</p> <p>5 A. I don't --</p> <p>6 Q. (By Mr. Faes) Deciding -- I think I</p> <p>7 flubbed the end of that question. I meant to say</p> <p>8 deciding what to do with their patients. I don't</p> <p>9 know if the realtime is wrong or I'm wrong, but do you</p> <p>10 want me to answer the -- re-ask the question? It's a</p> <p>11 long one.</p> <p>12 A. Please.</p> <p>13 Q. We'll make this the last question then.</p> <p>14 A. Yeah.</p> <p>15 Q. If Ethicon medical affairs believed that a</p> <p>16 caution should be used before putting a Proxima into a</p> <p>17 woman based on some fact about her demographics or her</p> <p>18 age or her level of prolapse or comorbidities or</p> <p>19 anything like that was specific that could be related</p> <p>20 to specific patients, should that information</p> <p>21 have been in the IFU, so doctors would have</p> <p>22 that information when deciding what to do with</p> <p>23 their patients?</p> <p>24 MR. GAGE: Object to form.</p>	<p>1 A. Not necessarily.</p> <p>2 Q. (By Mr. Faes) You say not necessarily. Are</p> <p>3 there --</p> <p>4 A. Uh-huh.</p> <p>5 Q. -- are there situations where you believe it</p> <p>6 would be appropriate to not include a warning or</p> <p>7 precaution that medical affairs thought should be in</p> <p>8 the IFU for marketing reasons?</p> <p>9 MR. GAGE: Object to form.</p> <p>10 A. It depends on -- it depends on what it was.</p> <p>11 You know, when they're coming up with these things,</p> <p>12 they're taking in numerous considerations, so it would</p> <p>13 -- it would just depend on what it was. It would --</p> <p>14 it would give me some pause if that was the only</p> <p>15 reason for marketing reasons, but I would have to know</p> <p>16 more specifics before I drew a conclusion about it.</p> <p>17 Q. (By Mr. Faes) So if medical affairs said, I</p> <p>18 think this warning or precaution is really important</p> <p>19 and marketing comes in and says, yeah, but it's going</p> <p>20 to hurt the sales of our product, so we're not going</p> <p>21 to put it in, you believe that there are situations</p> <p>22 where that would not be wrongful?</p> <p>23 MR. GAGE: Object to form.</p> <p>24 A. Right, because as I've said before, there's</p>
Page 131	Page 133
<p>1 A. Again, it goes back to, what do you need to</p> <p>2 put in the IFU, because that's why we're physicians.</p> <p>3 We're professionals. We're trained to make these</p> <p>4 judgment calls. I mean, I think it -- I think that</p> <p>5 the IFU is perfectly adequate. I don't think anything</p> <p>6 was left out, so I can't think of what they would come</p> <p>7 up with that would change that opinion that I would</p> <p>8 say -- I would say no to that question, because,</p> <p>9 again, they're going to be discussing things back and</p> <p>10 forth and bouncing ideas off of each other. That</p> <p>11 doesn't all need to go into the IFU.</p> <p>12 Q. (By Mr. Faes) But if Ethicon medical affairs</p> <p>13 believed that that caution should be put in there, you</p> <p>14 believe that that information doesn't need to be</p> <p>15 included, even if Ethicon medical affairs believes</p> <p>16 it needs to be put in there?</p> <p>17 MR. GAGE: Object to form.</p> <p>18 A. As I already answered, I would say no.</p> <p>19 Q. (By Mr. Faes) If Ethicon medical affairs</p> <p>20 believed that a particular warning or caution should</p> <p>21 be added to the IFU, but that caution or warning</p> <p>22 wasn't added due to marketing reasons, would you agree</p> <p>23 that that would be wrongful?</p> <p>24 MR. GAGE: Object to form.</p>	<p>1 some risks that are not in an IFU for any product that</p> <p>2 surgeons are aware of, like death. Death is a risk of</p> <p>3 any surgical device with surgery. You know, surgery</p> <p>4 has a risk of death, so they may not want to put that</p> <p>5 in there for marketing reasons.</p> <p>6 Q. (By Mr. Faes) So you believe that there are</p> <p>7 situations where it's appropriate for marketing to</p> <p>8 override the judgment of medical affairs?</p> <p>9 MR. GAGE: Object to form.</p> <p>10 A. I don't -- I don't -- I don't want to agree</p> <p>11 with that. I mean, I don't want to disagree with that</p> <p>12 because medical affairs should be the priority, but</p> <p>13 there are so many considerations that go into it.</p> <p>14 MR. FAES: I'll object and move to</p> <p>15 strike after the word "priority." And Doctor, I'll</p> <p>16 let you go, because --</p> <p>17 THE WITNESS: Okay.</p> <p>18 MR. FAES: -- I'm sorry. I asked way</p> <p>19 more questions than I intended to. We got into a --</p> <p>20 THE WITNESS: I know. We were on a roll</p> <p>21 there.</p> <p>22 MR. FAES: We got into a thing there.</p> <p>23 THE WITNESS: Yeah.</p> <p>24 MR. GAGE: All right. So we're off the</p>

34 (Pages 130 to 133)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 134</p> <p>1 record now. 2 (Deposition concluded at 4:25 p.m.) 3 (Signature reserved.) 4 * * * * * 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>	<p style="text-align: right;">Page 136</p> <p>1 ACKNOWLEDGMENT OF DEPONENT 2 3 I, _____, do 4 hereby certify that I have read the 5 foregoing pages, and that the same is 6 a correct transcription of the answers 7 given by me to the questions therein 8 propounded, except for the corrections or 9 changes in form or substance, if any, 10 noted in the attached Errata Sheet. 11 12 13 _____ 14 CHRISTINA PRAMUDJI, M.D. DATE 15 16 17 Subscribed and sworn 18 to before me this 19 ____ day of _____, 20____. 20 My commission expires: _____ 21 22 _____ 23 Notary Public 24</p>
<p style="text-align: right;">Page 135</p> <p>1 - - - - - 2 E R R A T A 3 - - - - - 4 5 PAGE LINE CHANGE 6 _____ 7 REASON: _____ 8 _____ 9 REASON: _____ 10 _____ 11 REASON: _____ 12 _____ 13 REASON: _____ 14 _____ 15 REASON: _____ 16 _____ 17 REASON: _____ 18 _____ 19 REASON: _____ 20 _____ 21 REASON: _____ 22 _____ 23 REASON: _____ 24 _____</p>	<p style="text-align: right;">Page 137</p> <p>1 THE STATE OF TEXAS: 2 COUNTY OF FT. BEND: 3 4 I, Tamara Vinson, a Certified Shorthand 5 Reporter and Notary Public in and for the State of 6 Texas, do hereby certify that the facts as stated by 7 me in the caption hereto are true; that the above and 8 foregoing answers of the witness, CHRISTINA PRAMUDJI, 9 M.D., to the interrogatories as indicated were made 10 before me by the said witness after being first duly 11 sworn to testify the truth, and same were reduced to 12 typewriting under my direction; that the above and 13 foregoing deposition as set forth in typewriting is a 14 full, true, and correct transcript of the proceedings 15 had at the time of taking of said deposition. 16 I further certify that I am not, in any 17 capacity, a regular employee of the party in whose 18 behalf this deposition is taken, nor in the regular 19 employ of his attorney; and I certify that I am not 20 interested in the cause, nor of kin or counsel to 21 either of the parties. 22 23 GIVEN UNDER MY HAND AND SEAL OF OFFICE, on 24 this, the ____ day of March, 2016. 25 26 _____ 27 Tamara Vinson, Texas CSR No. 3015 28 Expiration Date: 12-31-2016 29 30 GOLKOW TECHNOLOGIES, INC. 31 Texas CRCB Registration #690 32 440 Louisiana, Suite 910 33 Houston, Texas 77002 34 www.golkow.com</p>

35 (Pages 134 to 137)

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abdominal 34:20 35:7,16 36:8 68:14,15 100:9,9 101:1,5,6,9 abdominally 61:13 62:2,21 93:7 able 36:23,24 46:5 51:19 103:6 112:15 118:5 122:24 abovestyled 3:4 absolutely 28:1 43:3 48:22,24 51:22 52:1 56:6 69:24 77:19 92:21 118:16 126:14,17 accelerate 80:6 accept 45:15 acknowledging 90:7 acknowledgment 136:1 add 126:9 added 56:24 57:17 58:13 125:11 131:21,22 addition 6:7 additional 59:2 64:18 address 6:20 22:4,7 22:10 23:7,10 65:21 adequate 114:19,20 115:10 131:5 adequately 114:21 adhesions 62:22,23 100:22 advantage 39:3 adverse 59:24 afaes 4:6 afc 35:18 affairs 114:9 115:1 129:6,19 130:15 131:12,15,19 132:7,17 133:8,12	afternoon 7:5 age 129:22 130:18 ago 18:21 28:13 33:9,13 39:6 agree 9:11 10:11 11:6,15,19,24 12:20 13:1,6 17:5 23:13,15 27:19 35:7 41:3 44:17 46:14 54:22 56:22 58:3,6,22 59:5 61:12 62:12 63:13 64:3,9,19 65:18 66:8,10 70:1,3 78:6 79:11 80:23 82:7 83:19 86:16 89:15 90:9 94:1,3 94:9,11 96:3,7 102:2,17,21,22 103:10,15,21 104:2,4 110:23 111:8,12 112:4 114:24 115:5,23 116:2,7,11,12,22 117:12,18,22 119:4,5,15,17,22 120:2,8,13,18,22 121:2,4,8,13,19 122:10,19 124:7,9 127:20 128:9,14 131:22 133:10 ahead 40:19 allows 52:20 alternative 23:14 23:16 34:17 35:6 92:20 alternatives 32:15 35:8 ams 35:23 amsden 2:11 analyses 67:23 analysis 49:14 67:11,15,18 70:17 andrew 4:4 andy 7:6 9:23 19:14 34:1,1,6	angles 38:11 announce 28:15 announced 28:13 announcement 47:14 48:7 49:7 answer 13:14 18:13 22:22 34:4 40:14 42:18 58:2,5,21 59:4 71:15 72:22 78:4 80:5 82:19 106:8 115:24 117:5 119:12 120:7 121:18,23 126:18 128:23 129:1,2 130:10 answered 11:13 18:11,12 62:24 71:18 72:12 73:16 95:20 123:16 129:4 131:18 answering 34:6 answers 136:6 137:6 anterior 57:24 125:2,5,8,22 126:1,2 127:12 anticipate 8:24 49:11 98:19 103:6 112:16 122:13,17 122:24 anticipated 73:15 112:22 anybody 108:11 anymore 28:14 anyway 15:10 95:23 124:6 apart 76:8 77:3,6 apex 30:5 apical 29:24 30:3 37:19,20 38:1 50:24 57:15 101:16 apologize 107:5 apparent 104:8 appearances 5:3 applied 106:19,23	apply 109:15 appreciate 23:3 36:24 appreciates 34:10 apprise 106:15 appropriate 15:6 35:10 132:6 133:7 appropriately 56:19 approval 69:13 approved 52:17,24 53:7 69:8 approximately 88:2 area 23:22 24:3 105:24 123:11,12 124:19 125:7 126:3,11 areas 38:12 arent 52:23 109:6,6 arm 95:18 arms 125:8,9 126:10,11,20 arteries 76:15 article 104:11 articles 13:22 artisyn 36:2 asc 35:17,18 97:22 100:18 101:23 asked 19:1 22:14 40:8 71:14,19 75:20 107:5 122:2 133:18 askew 32:13 asking 79:10,11 98:15 assessment 68:6 assigns 67:22 associated 6:16 54:23 55:20 56:17 assume 108:24 109:9,16,18,23 assuming 10:5 83:17 84:7 astora 28:16 attached 3:10 7:23	136:10 attempts 121:5 attended 81:17 attorney 137:13 attributable 115:2 augmentation 64:17 august 25:2,20,23 authoritative 63:15 authoritive 63:14 available 9:11 23:18 26:10 28:22 30:22 31:1 32:4 36:15 37:9 42:1 44:14 46:17,24 47:9,10,16 48:8 49:7,24 50:10,18 98:20 124:18 125:6 127:8 avenue 4:5 avoid 38:23 102:3 102:19 aware 84:22,23 98:12,13 104:16 111:15,18 133:2 <hr/> B babbling 75:23 back 8:12 9:23 19:7 25:24 27:8 40:3 41:16 57:15 69:19 71:5 97:11 115:8 131:1,9 background 110:23 backgrounds 115:13 backtracking 53:10 bad 71:20 105:19 banks 1:20 barbara 1:9 bard 90:3 barker 2:2 based 96:14 97:2 97:17 129:21

130:17	big 18:17 80:19	buy 49:5,23	20:11,16,17 46:10	chemical 70:5,13
basically 50:22	bigger 126:2		65:16 69:23 87:5	chemistry 70:2,10
basis 75:5,13,14	billed 8:20	C	93:14 96:19	choice 30:16 36:9
123:7	billing 8:24	c 4:1	100:11 106:14	37:24 38:5,6,8
bathroom 97:5	bills 9:11	cadaver 32:22	114:8,18 117:15	51:4 97:21 98:21
bears 57:3 82:3	biofilm 76:10	calculating 84:16	cases 1:7 8:12	98:23 103:1,12
began 50:20 68:14	biologic 30:12	calculation 46:4	21:13 76:23	choose 13:22 102:3
beginning 66:1	biology 93:18	caliber 61:3	casespecific 8:18	102:18
behalf 137:12	bit 39:5 50:12	call 17:1 72:16	9:14	chose 10:23 36:17
believe 12:14 24:15	53:10 73:18 87:24	called 35:21 90:3	catherines 47:21	christina 1:13 3:1
24:18,20 25:10,15	106:7	110:18,19	cathy 2:10	5:5 6:3,5,7 7:1
26:2 29:4 39:12	bleeding 38:24 39:2	calls 131:4	cause 3:4 75:11	136:14 137:6
39:15 40:21 42:18	blood 94:20	cant 10:1 18:2 19:6	80:6 85:16,23	chronic 119:24
44:3 51:23 52:2	blynn 2:1	19:7 24:20 28:23	86:1,17,19 96:8	circles 127:24
52:14 53:14 54:8	body 44:22 79:9,11	29:7 31:17,20	101:11,13 115:3	circumstance 79:8
54:13,16 56:13,18	83:23,24 86:1,2,6	45:6 46:7 51:9	116:6 117:18,21	93:20
59:17 60:6 66:14	86:13 100:15	58:5 62:17 74:18	137:14	circumstances 78:8
66:17,20 71:3,7	103:20 110:6	74:18 88:17 92:17	causes 96:2,4	78:10,11 79:13
71:17,21,23 72:7	boggs 2:7	99:13 100:5 105:6	causing 86:2	cite 13:22,24
72:13,23 73:3,7	bogus 76:16	107:7 108:20	cautery 94:19	cited 13:23 104:10
73:16,20 74:1,8	borne 62:18	116:16 119:12	caution 129:7,20	city 3:8 4:5 47:19
77:5,8,10,12,13	boston 29:3,4	122:6 128:23	130:16 131:13,20	civil 3:9
78:13,15 79:17	bouncing 115:8	129:2,2 131:6	131:21	clarify 55:2
80:4,6,9,15 84:13	131:10	capacity 137:12	caviness 18:22	class 66:3,4,24 67:2
85:2,9,10,17	bound 111:17	caption 137:5	20:10	67:2 68:19 69:14
88:18 92:23 93:2	bowel 62:22 100:17	carbone 81:12,14	cavity 79:19,23	129:8
93:10 97:1,16	100:22 101:15,22	81:22 82:2	centimeter 125:23	classified 66:24
98:21 100:19,23	box 41:10	cardiac 76:14	centimeters 125:18	67:2
101:14,20 106:17	break 40:2,4,8	79:17,19,23	126:7,13,16	clean 34:7
106:22 110:15	72:13 85:11 86:15	care 51:24 52:15	certain 52:19 72:19	clear 64:16 101:2
116:5 124:17	97:6,10,12,15	53:8,9 64:20,23	107:2	clearance 41:14,22
125:5 126:3,12,15	breakdown 86:4,7	112:10 113:13,23	certainly 70:12	42:4,12
131:14 132:5,21	breaking 85:18	114:5	82:4 99:21	cleared 26:8 52:3,6
133:6	brenda 1:12	career 107:10,15	certificate 5:9	52:16,24 68:19,24
believed 60:3 129:6	brings 37:2,6	carey 2:8	certified 137:3	69:5,8
129:20 130:15	brittle 78:17 79:5	carol 2:23	certify 136:4 137:5	clinical 26:16 76:21
131:13,20	86:8,13,23	carpenter 1:14	137:11,13	76:22 77:7,20
believes 81:23	broadly 25:4	carry 100:24	change 74:15 131:7	78:2 93:22 94:7,8
131:15	broken 91:21	cartmell 4:4	135:5	clinically 78:11
bend 137:2	brought 7:24 8:3,5	case 1:8,10,11,13	changed 108:5	clock 129:15
benefit 38:21 56:24	8:5,14 16:6,13,17	1:14,16,17,19,20	changes 108:3	close 34:23
57:17,24 58:13,18	bullet 57:12 58:6	1:22,23 2:1,3,4,6	136:9	closed 118:2
58:19	59:20 61:23 62:1	2:7,9,10,12,13,15	changing 107:4	closer 81:2
best 37:18 39:6,11	butler 4:9 8:13	2:16,18,19,21,22	charlene 2:20	cole 2:8
better 63:4 64:8,16	16:1 19:1	2:24 16:4 18:15	charleston 1:2	colleagues 82:5,22
89:11 96:13	butlersnow 4:11	18:20,23 19:5	check 48:20	colony 4:10

coloplast 35:21 36:9	124:24 127:14,16	58:9	22:1,2 23:23,24 24:4,5,7,23 25:7 25:19 26:5,6,12 26:18,20 27:14 32:10 33:20,21 34:21,22 36:11 37:10,14 38:15,16 39:7 41:6,7,12,23 43:12,21,22 46:18 49:3,21 50:11 51:2 56:1,2 60:4 65:4 67:23,24 68:9,10 82:24 83:1,20 84:10,11 91:13,14 93:11,12 96:5,9,10,16,17 96:23 97:22,23 99:23 100:2 104:22,23 105:3 107:24 108:2 123:9,10,18,19 127:10 136:6 137:10	20:10 92:5 criteria 50:13,14 csr 3:6 137:19 cure 71:1 75:4 76:4 curious 114:8,12 current 21:24 currently 32:4 35:23 36:8 52:16 97:21 curriculum 6:9,12 23:6,10 cut 27:1,11 29:16 30:7 96:1 128:5 cv 8:5 21:16,18,19 21:24 22:3,16 cystocele 37:19 38:1 40:10 cytotoxic 93:11,17 93:23 94:10,15,24 95:10 96:9 cytotoxicity 93:19
colporrhaphy 63:16	34:1 61:6 79:7 118:2	consents 56:14,15 consider 30:12 42:23 51:21 52:7 52:10 54:5 61:23 67:6 83:2,10,18 84:8 111:1,23 113:22		
com 4:6,11 102:7 137:24	complex 119:19	consideration 105:24 106:1 109:4,16		
combine 10:24 11:5 125:1	complication 12:1 12:14 103:8 111:9 111:21 112:6,24 113:10,24 114:6 115:2	considerations 132:12 133:13		
combined 16:24 17:7,8 72:9 125:1	complications 6:15 23:23 24:3 39:1 54:22 55:5,8,20 56:9,17 61:14 62:3,14 71:19 73:21,22 74:2,10 80:16 100:17 102:4,6,8,19,24 103:4,7 107:2 109:2,11,20 110:5 110:13 111:16,18 112:16 114:22 115:12 120:11,15 121:10 122:1	considers 83:4 consulted 56:3 contacted 18:15 20:15 contain 10:19 16:2 contained 40:21 57:9 125:23 continue 34:13 50:8 51:24 continued 48:6 49:19		
come 11:11 131:6		contract 59:15,18 60:7,13,15	correction 60:10	D
comes 81:3 132:19		contracted 118:13	corrections 136:8	d 1:13 3:1 5:5 6:4,5 7:1 136:14 137:7
comfortable 52:13 67:8 70:6		contracting 61:2	correctly 24:15 75:2 76:18 103:16 125:18	daphne 2:2
coming 132:11		contraction 59:13 59:15,20 60:4,9 116:3,5,7,8,12,13 116:23,23 117:2 117:12,13	correlates 11:3 68:2	data 44:22 52:11 69:21 74:16 76:1 76:6
commentary 9:23		contracts 59:16,16 59:17 60:16,19 61:7	correlation 74:12	database 81:11
commercials 32:13		contrast 41:9	couldnt 21:20 45:9 45:10	date 25:16 26:5 28:23 37:12 41:14 41:22 42:4,12 48:21 49:2 50:3 136:14 137:20
commission 136:20		controlled 14:2 87:15 91:4,10 92:8,15,19,23	counsel 9:24 21:18 92:4 137:14	dated 65:22
communicate 110:8		controversial 35:1	counting 32:22	dates 25:7,14
communication 6:17		converse 75:17	country 115:13	day 122:3 136:19 137:16
comorbidities 129:23 130:18		corporate 28:18	county 137:2	days 9:3,4 103:24 104:8
companies 110:16		correct 7:10 11:20 12:2 13:4,5 15:22 17:10,13 19:5,11	couple 28:13 33:12 36:4 107:6	deal 10:10
company 8:7 39:19 109:2,10,11,13,19			course 41:13 111:4	dealt 70:4
comparable 63:16			court 1:1 4:14 9:17 19:19 20:3 33:24 34:9	death 133:2,2,4
comparator 92:16			crcb 137:21	decide 37:17
compare 11:23 36:22 83:24 87:17 89:6,18 92:24 127:19			created 19:10	deciding 130:2,6,8
compared 23:17 36:14,21 38:22 56:24 57:17 58:14 61:14 62:3,14 100:8,17 124:9 127:4,20 128:9,14				
comparing 92:15 92:19 127:13,14				
comparison 89:20 127:18				
compartment 72:4 72:5,8,9,11,15,24 73:5,9,9 74:3				
	conclude 134:2			
	conclusion 132:16			
	conclusions 18:2			
	conductive 27:22			
	conducting 26:11 26:15			
	configurations 32:3 123:17			
	configuring 124:15			
	confused 16:16 25:8,14 31:6			
	conjunction 30:2			
	consent 36:12			
	consented 56:19			

130:22	deponent 136:1	devices 37:16,16	disappear 76:13	75:17,18 76:12,13
decision 13:21 54:9	deposed 107:6	43:6 46:19 47:24	disappearing 85:15	76:20 77:12
54:14,17 66:11	deposition 1:12 3:1	48:10 49:6 51:24	disclose 110:4	100:24 101:14
decreased 58:19	6:3 7:6,19,20 9:17	66:3,4,5,9 67:12	disclosed 110:14	131:11,14
defect 29:24 30:10	14:9 40:12 55:12	67:16 91:7,13	115:5	doing 27:12 34:23
defects 39:7,16	65:8 134:2 137:9	93:5 111:1,5	disclosing 109:1,11	42:23 101:18
defendants 4:8	137:11,12	diabetes 94:20	109:19	111:14 112:9
defining 55:1	depth 89:14	didn't 14:17,24 15:7	disclosure 19:12	114:7
definitely 38:8	details 10:1	18:5 19:4 24:19	disclosures 19:20	donna 2:11
58:19 71:4	determination	24:21 26:3 30:10	discomfort 86:24	dont 7:14 9:21 10:6
deformed 61:5,9	87:17	36:4,5,22 37:4,4	discontinuance	11:21 13:10 14:16
degradation 70:24	determine 67:11,15	39:1 49:8,10,13	37:13	15:9 19:6,16
71:6 74:24 76:9	70:20 88:3,23	50:5 75:21 77:1	discuss 10:10 13:17	25:10 30:17,17,17
76:16 80:3	89:10	79:1 82:19 89:14	13:17	30:19,24 31:13,22
degrade 74:19 75:6	devastating 103:9	89:23 90:8 111:22	discussed 43:8 86:9	32:2 33:9 34:22
75:16 76:13,20	developed 128:17	113:1,11 114:1,5	119:8	35:12 36:2,22
77:13,19 78:1,7,9	developing 98:8	122:16	discussing 131:9	41:19,20,21,24
78:10 79:13 80:7	device 7:7 11:19	difference 12:24	discussions 115:8	42:8,16,16 45:19
85:11,21,22	12:1,15,20 13:9	15:9 21:20 31:14	disintegrating 77:3	46:21 47:1 48:11
degraded 76:14	15:21,21 24:13,21	31:22,24 38:17	77:6	48:13,16 52:5
degrades 69:22	26:3,8,12 36:13	differences 11:18	dispute 10:1,2,8	53:16,19 54:7
70:15,20 74:11,17	37:8,24 38:4,6,8	37:1	dissection 100:16	59:17 63:10 64:8
75:19 76:2,7	38:14 39:6,11	different 11:7,9,11	101:17	66:10 67:4,20,21
77:18,24 78:6,14	40:9 42:20,24	11:15,22 12:2,12	distinction 53:4	68:1,4,6 69:2,3,8
78:16 86:13	43:6,12 46:23	12:21,23 15:3	118:7,19	71:5 72:16 74:7
degrading 85:14,17	48:7,14 49:17	18:1 20:13 31:5	district 1:1,1,5	77:16,18 78:22,23
degree 61:11 72:19	50:6,9,14,15 51:4	36:22 37:1 38:11	division 1:2	82:3 83:6,24
80:1 107:2	51:4,20 52:2,16	38:12 71:15 72:9	doctor 10:13 41:14	85:21 88:5,5,10
demographics	52:23 54:10,18	73:4,9,19 77:9	42:19 54:9,14,17	88:13,16 90:19,24
129:22 130:17	66:12,15,18,21	79:7,20 89:8	65:1,7 69:18	91:16 92:9,13
demonstrate 91:5	67:3,19 68:3,9,18	92:24 112:12,13	80:19 102:2,17,22	93:8,10 95:1,3
91:11 93:4	68:20,24 69:5,14	113:18 119:7	103:3,11 111:11	99:5 107:23,23
demonstrated	71:8 80:10,16	diligent 111:23	112:8 129:7	109:7 110:9,19
96:14 97:1,16	81:24 84:14 92:16	dimock 2:23	133:15	111:12 112:20
demonstrative	92:19,20,24,24	dinner 81:20	doctors 106:15	113:4 117:15
91:23 92:5	98:9,21,23 99:4	direction 137:9	111:1,5 115:12	118:18 119:6
department 114:9	100:23 101:8,11	disagree 44:21	130:1,21	122:7,9,9,22
depend 86:11	101:14 102:1,5,20	55:24 56:22 57:2	document 1:6 7:21	123:16 124:4
105:19 112:1	102:24 103:1,16	57:21 58:4 60:7	7:24 40:13 65:13	126:5,8,11,19
132:13	103:17,22,23	60:11 61:12 62:6	65:15,19	129:3 130:5,8
depended 124:14	104:7 106:9	62:17 63:13,17,20	documentation	131:5 133:10,10
128:1	107:12,16,20,24	64:19,23 66:11	89:2 91:17	133:10,11
depending 38:10	109:3,10,19 110:1	81:7 82:1 83:20	documents 8:6,8	dozen 27:5
103:19 128:5	111:10,21 112:24	84:2,10 114:3	83:13	dr 7:5,20 15:11
depends 11:17	113:10 114:1	127:4,10 133:11	doesn't 59:15 63:9	23:5 40:3 81:12
125:19 132:10,10	123:8 133:3	disagreed 56:7,9	74:16 75:1,6,15	81:14,22 82:2,22

83:2,4,7,11,18,23 84:8 97:11 drafting 21:8 draw 18:2 drawing 13:18 drew 132:16 drives 8:7 16:9 due 82:2 83:22 94:18 131:22 duly 3:3 7:2 137:7 durham 1:23 dynamesh 96:22 dyspareunia 120:4	88:14 98:4 elizabeth 2:1 email 28:16,19 employ 137:13 employee 137:12 encapsulated 60:21 engage 117:7,14,17 117:23 engineering 70:5 ensure 41:8 enterocele 101:17 entire 21:3 124:19 126:23 entitled 124:3 environment 27:16 27:22 32:7 79:18 79:19 eroded 86:2 erosion 61:16 64:18 80:23 81:5,23 82:8,13,23 85:12 85:16 86:10,17,19 94:4,13,14 95:3,4 95:7,14 105:2,5,7 105:9,11,12,16,22 105:23 122:14 erosions 71:10 94:22,24 105:19 119:19 120:19,23 121:21 errata 136:10 especially 118:11 esq 4:4,9 essman 1:8 estimate 20:22 21:2 26:23 ethicon 1:3 26:5,17 35:19 36:2 40:24 41:10 45:14 46:15 46:19 47:24 49:18 53:17 63:19 67:10 67:14,22 69:10 81:17 83:9,10 98:8 106:19,22 108:10,10,12 114:10,24 122:3	122:19 129:6,11 129:19 130:15 131:12,15,19 ethicons 44:14 45:7 45:12 68:6 eugenia 2:5 event 59:24 evidence 56:23 57:13 58:13 74:10 93:10 94:15 exact 88:16 91:15 exactly 42:15 examination 5:6 7:3 examine 51:17 examining 76:24 example 11:7 13:1 28:3 79:12 86:9 exception 8:11 122:14 excise 121:5 excluding 73:22,23 excuse 107:1 exhibit 6:1,3,5,6,9 6:10,12,13,15,18 7:17,19 9:7,8,18 9:20 10:12,14 13:16 14:7,9,21 15:13 16:22 20:24 21:14,16,18,21,22 21:23 40:7,11 41:4 55:10,12 61:20,21 65:1,6,8 68:11 69:20 exist 60:4 experience 52:11 55:7 57:7 63:23 67:9 74:6 76:21 76:22 82:4 84:1 104:12 110:24 111:10 112:13 113:16,21 115:14 experienced 111:7 111:16 123:7 expert 6:5 8:15 10:17 18:15 19:2	19:12 20:16,19 24:20 70:1,9 experts 10:3,9 75:22 96:12 expiration 48:21 49:2 50:3 137:20 expired 50:4 51:20 expires 136:20 exposed 86:2 93:17 94:10 96:8 exposure 59:3 62:20,20 64:18 81:5 82:8,13,16 82:20,23 85:12,16 86:5,7 94:4,13,14 105:7,17 extent 50:5 external 38:19 extra 49:23 extrusion 73:17 80:23 81:5,23 extrusions 120:24 eyes 77:4,7	53:3 56:22 58:22 59:12 60:11,18 64:8,19 65:7,9,11 71:17,18,21 73:13 77:21 78:20 80:2 82:18,21 83:16 84:4,13 87:16 90:9 92:4,7 97:7 97:11 99:3,14,21 100:3 102:14,17 107:10,19 110:11 111:8 112:19 113:17 114:7,16 116:20,22 117:4,6 117:10 119:22 120:6,8 121:13,17 121:19 123:1,3,15 123:22 124:1,5,7 124:17 127:11 129:1,17,19 130:6 131:12,19 132:2 132:17 133:6,14 133:18,22 failure 71:24 72:1,2 72:17,24 73:4,8 73:22,23 74:3,8 failures 72:14 fair 31:21 36:7 37:23 62:6 83:11 90:16 103:14 fall 103:17 falling 77:3,6 familiar 21:13 54:7 82:11 104:21 far 26:14 70:11,11 fashion 30:3 fashioned 125:19 faster 129:15 fault 72:18 fda 6:17,18,18 45:1 45:15 52:3,17,24 53:7,12 54:10,18 55:19,24 56:9 57:22 58:4 59:24 60:2,12 62:7,13 65:19 66:2 69:13	
E					
e 4:1,1 135:2 earlier 25:10 32:6 42:6 75:21 119:8 127:2 early 98:14 easy 99:6 121:21 ed 39:13 edge 86:20 edges 86:16 94:19 education 40:22 41:9 educational 8:7 effect 77:20 80:3 93:22 94:9 100:15 effective 44:23 52:12 57:4 64:1 efficacious 63:22 96:14 97:2,17 efficacy 11:7,9,13 12:21 17:20 18:9 44:19 63:5,10 eight 81:2 123:20 either 24:4 26:4 30:11 37:12 41:22 42:12 73:8 110:10 125:8 137:14 elapsing 104:8 electron 77:1 elevate 28:5,8 29:10 33:2,3 38:14,20 87:23					
				F	
			f 1:20 fact 35:8 38:19 75:3,15 79:15,21 81:16 99:14 129:21 130:17 factors 37:21 61:24 105:23 facts 13:16,17,17 137:5 faes 4:4 5:6 7:4,6 10:11,13 13:13,15 14:14,19,23 15:2 15:9,11 18:3 19:9 19:22 20:2,4,8,9 20:12 22:17,20 23:2,5,21 25:4,9 25:22 34:9,12 35:14 36:7 37:2 39:22,23 40:3,20 44:24 45:20,24 46:9,14 52:14,22		

83:4,9,10,17,20 83:22 84:7,10 110:16 114:11 fdas 44:17 45:14 66:11 federal 3:9 20:3 feel 29:1 30:10 52:13 67:8 69:19 69:24 70:6 105:10 127:24 feeling 27:18 90:13 felt 13:18 22:22 49:9 50:18 fibers 61:4 fifteen 43:17 fifth 55:18 fight 10:10 file 1:3 find 8:10 24:20 51:19 80:21 88:7 88:11,14 106:4 fine 114:22 124:2 finish 34:2 finished 34:6 first 7:2 18:12,14 20:15 21:19 24:12 25:12 32:16,19 33:8 35:2 41:18 42:1 47:14 65:12 66:1 68:12,18,23 69:4,9 72:17 75:14 100:13 108:1 122:4 123:6 137:7 fishing 78:20,23 79:2,4 86:9 five 71:9 73:24 74:4 74:10 80:17 81:2 93:2 107:7 flash 16:9 flat 11:8,16 12:2,6 12:15,22 13:2,8 27:3,4 28:3,4 29:16,21 41:15 43:24 44:8,13 53:11,18 66:20	67:2 68:7,18 69:4 69:11 85:1 92:12 92:15 106:11 124:18 floor 59:11 60:10 81:17 flow 94:21 flubbed 130:7 following 1:7 54:10 54:18 63:14 follows 7:2 followup 84:23 foregoing 136:5 137:6,9 forget 14:16,18 15:7 forgot 33:15 forgotten 75:22 form 17:19,21 18:8 22:12,13 23:19 25:3,6,21 35:11 36:3,18 39:17 44:20 45:17,22 46:3,12 52:8,18 53:2 56:20 58:15 60:5,14 64:6,14 71:13 73:11 77:17 78:18 79:24 83:12 83:21 84:2,12 87:13 94:16 98:24 99:12,18 100:1 107:17 110:7 111:3 112:11 113:14 114:2,14 117:9,11 119:20 121:11 122:21 123:14 124:13 127:9 128:22 130:4,24 131:17 131:24 132:9,23 133:9 136:9 forming 16:3,18 17:15,17 18:6 65:16 67:6 114:17 forth 9:24 115:9 131:10 137:9	forward 27:8 found 46:22 four 55:18 89:4,9 105:16 fox 1:21 frame 84:16 free 27:1 30:3,7 69:19 frequency 107:2 frequently 50:21 front 16:10 41:4 77:3,6 ft 137:2 full 24:19,21 26:17 46:15 83:23,24 137:10 fully 34:1 36:24 further 62:18 84:20 137:11 <hr/> G <hr/> gage 4:9,11 9:21 14:16,20,24 15:4 17:21 19:14,16,19 19:23 22:12,19,21 23:4,19 25:3,6,21 33:22,24 34:4,11 35:11 36:3,18 39:17 40:18 44:20 45:17,22 46:3,12 52:8,18 53:2 56:20 58:15 59:8 60:5,14 64:6,14 65:3,5 71:13 73:11 77:17 78:18 79:24 83:12,21 84:12 87:13 90:5 94:16 97:5 98:24 99:12,18 100:1 102:11,16 107:9 107:17 110:7 111:3 112:11 113:14 114:2,14 116:18 117:9 119:20 121:11 122:21 123:14,20	123:23 124:3,13 127:9 128:22 129:15,18 130:4 130:24 131:17,24 132:9,23 133:9,24 gathering 14:3 general 9:13 11:10 11:10,24 15:17,20 17:10 18:4,15 20:19 36:16,20 generalized 9:23 generally 66:4,5 127:23 gessner 3:8 getting 80:12 give 65:11 71:15 132:14 given 136:7 137:16 giving 22:21 114:4 115:22 glance 21:19 go 13:16 30:5 39:23 40:19 41:1 50:5 59:19 61:23 84:18 84:20 85:3 89:14 119:14 123:21 131:11 133:13,16 goes 41:11,16 131:1 going 7:18 9:6,7 10:5,13 14:1,8 20:13 21:15,17 25:16 27:8,8 28:14 46:23 47:8 47:9,15 48:8 55:11,17 59:10 61:3,4,5 65:7 69:16 72:10,11,19 73:18 80:21 82:18 83:16 84:4,6 89:7 95:22 96:1 99:6 101:5 102:11,12 103:5 109:6,6,17 111:4,6 115:7,24 117:10 119:5 127:24 131:9 132:19,20	golkow 137:21,24 good 7:5 14:5 50:18 51:11 63:21 69:10 114:5 goodwin 1:4 gotta 129:12 gotten 10:2 grade 37:18,24 38:9,10,10 39:7 39:16 40:10 77:16 grades 39:11 graft 63:3 127:14 127:15,19 grafts 128:3 grams 100:4 grand 4:5 gray 105:24 great 52:1,9 greater 30:3 82:14 91:19 125:16 grossly 76:24 group 51:14 guide 110:16 guidelines 110:15 110:18,21 gut 90:13 guys 20:2,4 gyne 96:15 gynecare 6:14 gynecologists 68:14 gynemesh 10:18,21 11:3,8,16 12:2,3,5 12:13,15,22 13:2 13:8 15:16 16:19 17:4 18:6,9 20:16 22:7 23:7 26:19 26:24 27:1,3,7,10 29:21 30:6,18,23 31:1,15,23 32:4,7 41:15,17 42:13 43:24 44:4,8,13 53:10,18 54:1 66:20 67:1,7,19 68:7 69:1,4,11,22 70:7 74:11,17 76:2,7,20 84:24
---	--	--	--	---

87:3 88:1 89:12 90:11,14,22 91:6 91:11 92:12,15 93:4,6 96:15 97:3 97:18 98:10,17 99:11,17,24 100:4 106:11 108:18,21 114:18 115:2,16 119:11 123:17 124:15,18 125:2,6 125:15,23 126:22 127:14,15,19 128:1,3,5,12,17 128:18	heard 9:23 104:3,6 heather 2:13 heavier 99:10,22 held 11:12 hell 15:4,5 help 27:12 110:16 helped 16:1 helpful 114:17 helps 17:24 hereto 3:11 137:5 hermann 47:19,21 hernia 54:1 100:21 100:24 101:1,6,12 hernias 68:14 101:12 hes 117:10 high 68:3 71:2 75:5 76:4 80:11 81:8 81:11 82:4,5,6,8 84:15 105:2,7,9 105:14 106:5,7 higher 81:9 106:2 highest 14:4,5 highland 4:10 highrisk 66:5,9,12 66:15,18,21 68:8 hill 1:9 history 94:20 hold 70:9 holes 95:10 honestly 19:6,16 hospital 47:22 49:5 hospitals 28:24 47:12,18,23 49:17 49:23 hours 20:12,23 21:2,3,7,10 123:24 houston 3:8 137:23 huge 12:24,24 human 33:1 hundred 91:5,11 91:19,22 92:8 93:3 126:15 hurt 132:20 hypothetical 63:7	74:20 83:17 84:7 hypothetically 85:13,20 86:3,14 86:22 104:4	20:13 21:15,17 22:15 34:5 39:20 44:10,15 45:3,9 45:18 52:4,22,23 53:24 54:7 55:11 55:17 58:2 65:7 67:17 69:16 71:15 72:12 73:18 75:23 78:4 79:11 82:18 83:14,16 84:4,6 85:15 86:12 87:1 88:16 89:6 90:6 93:18 95:6,6,16 95:16,22 99:1 100:2 101:1 102:11 108:17 115:24 119:5,10 124:24 126:6 130:9 133:18 impact 77:7 78:2 78:12 implant 48:21 51:24 53:6 implanted 24:9,12 25:12 49:1 51:12 52:16 79:8,11 implanting 37:15 51:21 52:7 68:15 108:7,9 113:11 123:8 implants 27:18 implication 77:22 important 13:18 22:23 67:5 103:10 132:18 improper 94:19 improved 63:9 inability 117:6,7,14 incapacitating 121:15 incision 95:11,14 101:4,10 include 107:4 109:24,24 132:6 included 106:19,23 109:7 125:8,9	131:15 includes 66:4,5 including 8:6 incorrect 22:22 25:10,13 indelicate 118:20 index 5:1 6:1 indicated 39:16 40:10,16 42:21 43:24 44:4 52:23 103:23 137:7 indication 68:18,24 69:6,12,13 indications 43:1 ineloquent 87:12 infection 103:21 104:8 inflammation 93:24 inflammatory 85:23,24 86:3 inform 55:19 information 40:21 80:12 84:6 108:4 130:1,2,20,22 131:14 informed 103:1,12 inguinal 101:12 inherent 64:5,12 109:20 injury 100:21 101:15,19,22 115:4 innumerable 94:21 inserted 29:16 instance 3:2 83:19 84:9 intend 46:10 69:23 87:4 91:18 92:1 93:13 100:10 106:13 intended 133:19 intepro 89:24 97:24 98:2 intercourse 116:14 116:24 117:8,14
---	---	--	--	--

117:17,19,21,22 117:24 118:5,8,10 118:14 interested 137:14 internal 67:11,15 interrogatories 137:7 interrupt 14:24 15:6 18:5 48:24 100:2 intervention 120:24 interventions 120:10 intraabdominal 62:23 introduce 13:7 introduced 63:6 introduces 58:24 59:2,9 invasive 100:8 102:2,3,4,18,20 investigator 63:18 63:24 invoices 8:14 10:3 involved 26:15 107:11,15 isnt 80:19 94:7,13 113:20 issue 94:23 issued 15:19 45:1 53:12 56:5 66:2 issuing 55:19 ive 13:16 28:5,5 35:19,23 75:21 76:23 83:13 104:3 132:24	joy 1:8 judge 1:5 judgment 43:4,10 131:4 133:8 july 54:10,18 58:10 <hr/> K <hr/> k 1:20 kansas 4:5 katy 47:21 keep 89:2 96:1 keeping 50:2 keeps 41:1 kept 48:5 key 2:19 kin 137:14 kind 37:2,6 49:10 50:15 87:12 89:8 89:15 105:20,24 kit 13:2,7 29:7,18 32:16,19,21,22 33:2,11,18 36:12 36:17 37:17 56:16 99:8 107:20 109:3 109:10 110:6 111:10 112:17 124:20 kits 36:15,22 37:1 44:19,23 87:22 99:7,15 123:12 127:8 knew 22:24,24 109:2 111:20 115:1 122:3 know 7:14 9:6,22 10:7,9 11:21 13:10 14:3 17:23 19:6,16 24:16 26:7,14 29:1 30:17,17,18,19,24 31:3,12,14,18,22 32:2,3,12 34:22 35:14 39:10,13,18 40:24 41:14,17,20 41:21,24 42:4,8 43:23 45:18 46:19	47:23 48:3,13,17 49:11,17 52:5,9 53:17 54:7 57:6 63:10 66:23 67:1 67:4,10,14 68:1,4 68:6,23 69:2,3,7,8 69:10,16 76:12,24 77:2 78:20,23 79:1,21 80:2 81:8 81:12 82:13,21 83:4,6,13 84:18 88:20 90:20,24 91:15 92:7,11,14 92:18 93:6,19 95:7 98:8 99:3,5 99:15 100:3,6 102:23 103:4,11 104:24 105:4,21 106:18 107:1 108:4,15,18,21 109:5,21 110:2,3 110:18,19,20 111:9,11,12,22 112:2,6,7,12 113:1,11 114:1,5 115:22,24 119:14 122:2,7,9,10,19 123:11,11,16 124:4 125:1,21 126:5,11,21 129:3 130:9 132:11,15 133:3,20 knowing 103:5 111:24 knowingly 52:15 knowledge 16:23 17:24 49:1,4 52:20 113:16,21 122:23 known 109:13 115:12 kriz 1:11 <hr/> L <hr/> label 42:24 43:5,7,8 43:15,19 52:21	labs 32:23 lap 15:8 lapsed 103:18 large 14:3 29:24 30:10 81:10 121:21 launch 24:19,22 26:17 37:12 46:15 launched 24:17 25:2,4,20 26:4 41:18 law 41:4 lead 85:11,18 86:10 86:23 94:4,12 116:3,8,13,24 117:13 119:18,24 120:3,10 learn 28:15 leeway 52:20 left 99:7 131:6 legally 53:5 level 13:24 14:4,5 129:22 130:18 levels 115:13 liability 1:4 lieu 45:16 life 48:17 49:12 102:4,6,7 107:4 lifechanging 102:7 102:19,23 103:9 120:15 121:9 lighter 99:16,20 liked 98:15 limited 26:10 line 78:20,23 79:5,5 86:9 94:22 95:2,8 95:8,12,15 135:5 list 6:7 14:12,22 15:15,23 16:1,2 17:1,8,12 22:1 91:18,22 122:1 listed 16:22 22:3,6 22:15,16 23:6,9 42:12 96:2 lite 89:24 98:2 literature 8:7,8	13:11 14:1,4 23:22 24:3 39:18 55:6 56:12 57:2 59:23 60:3,12 62:10 63:21 64:15 67:9 71:4,6 74:5 76:19 82:3 83:23 84:1 89:9 96:15 97:3,18 105:21 litigation 1:5 32:13 little 16:16 29:10 39:5 42:6 50:12 53:10 73:18 106:7 113:18 live 33:1 105:22 llp 4:4,9 logan 2:20 lois 1:23 long 2:13 30:19 130:11 longer 37:9 46:17 46:23 47:9,15,16 48:8 49:6 50:9 52:24 longest 84:22,23 longterm 123:7 look 16:16 19:7 21:23 25:24 32:13 32:15 39:19,21 40:1 42:14 59:8 62:10 68:11 83:23 83:24 90:15 100:6 looked 15:8 90:19 91:1,2 looking 13:11 52:11 55:6 61:18 74:5,5 81:10 loss 37:19 38:1 50:23 lot 11:3,10 14:3 21:12 34:5 81:3 84:5,19 88:22 105:21 125:12 louisiana 137:22 low 68:3,8 71:1 75:4 76:3
---	---	--	---	--

lower 61:14 62:3,9 62:13	master 1:3	11:16 12:2,6,15	100:4 106:11	117:4 120:6
	material 109:21	12:22 13:3,3,7,8	107:20 109:10,21	121:17 123:1
M	materials 6:7 7:24	18:1,4 23:22 24:3	110:6 111:9 115:2	133:14
m 1:13 3:1,5,5 4:9	8:3,11 16:2,7,9	27:4,17,18,20,23	116:2,8,13,23	moved 27:19
5:5 6:4,5 7:1	21:11,12 40:22	28:2,3,5 29:3,3,4	117:2,13 119:19	multiple 57:4 80:14
18:17,17 31:6	41:1,10 91:20	29:16,21 30:3,7	121:5 123:8,12,17	96:2,4 115:7
33:16 50:6,9,15	matter 61:1 72:20	30:12,13,16 31:12	124:10,11,18,19	120:10,19 121:5
50:17,20 51:1,4	mdl 1:7 6:8 18:17	31:15,16,23 32:13	125:7,12,21	
54:18 98:9,11,15	mean 14:21,24	32:16 35:1,24	126:24 127:5,6,21	N
98:17,19,23 99:4	17:23 18:5 20:17	36:1,2,9,12,16,19	127:22 128:10,11	n 4:1,4
115:20 134:2	20:18,19 22:17	41:15 43:12,14,19	128:13,15,16,19	name 7:5 29:7
136:14 137:7	29:20 32:11 51:12	43:24 44:4,9,13	meshes 28:2 35:16	nancy 2:16
machine 3:7	53:22 55:2 61:1	44:19,23 53:11,18	35:17 36:1 87:16	narrow 57:23
major 17:22 100:21	62:12 70:3 72:1,2	53:21,23,24 54:3	89:4,10 96:13,13	native 27:13 30:11
majority 95:2	75:13,18 76:13	54:5,23 55:20	96:24 97:15	34:14,16 63:4
making 13:21	87:8,9 100:14	56:18,23,24 57:1	met 81:14	64:3,9,20 82:17
28:22 46:16	118:11 125:17	57:3,16,18 58:13	meter 100:4	90:9,20 112:17
118:19	126:5 131:4	58:14,18,20,22	methodology 88:24	117:2 118:12
manifestation 94:7	133:11	59:3,13,15,17,20	micral 103:20	necessarily 72:17
94:8	meaning 22:16	59:22 60:3,7,12	microscopic 70:17	75:17 109:14
manufactured	55:8	60:15,17,21,23	77:1	110:24 132:1,2
108:10	meant 23:1 102:7	61:2,8,12,14,15	microscopically	necessary 103:23
manufacturer	110:9 130:7	61:16,18,24 62:1	77:19 78:2	necrosis 93:24,24
36:14	medical 8:9 26:19	62:3,5,14,15,20	microscopy 77:1	94:11,17,21 96:3
march 1:14 3:4	42:20,24 43:12	62:21 64:4,5,11	midurethral 17:16	96:4,8
137:16	52:16 53:21 60:3	64:12,16,18 65:20	17:18 18:7	necrotized 94:1,3
maria 2:5,17	60:12 66:3 67:16	66:8,12,20 67:2	mind 50:2	94:12
marie 1:20	93:18 107:12,16	68:7,12,15,18,24	minds 10:4,6	need 10:10 28:2
mark 9:8 14:20	109:10,19 111:1,5	69:4,5,11 70:14	minimally 100:8	29:2,13 38:12
21:17	115:1 129:6,19	70:14,18,18,19,23	minute 39:6 85:5	39:24 44:18 49:13
marked 7:17,18	130:15 131:12,15	71:24 72:1,1,16	minutes 123:20	50:3 71:10 90:5
9:20 10:12,14	131:19 132:7,17	72:18 73:17 74:11	124:4	103:3 105:8
13:16 14:7,9 15:3	133:8,12	75:6 76:11,12,24	missing 113:15,16	129:13 131:1,11
20:24 21:14,16,22	medication 43:7	76:24 77:2,5,14	113:21	131:14
40:7,11 55:10,11	medications 43:5	78:13 84:24 85:1	mississippi 4:10	needed 10:4 29:13
65:6,8 69:20	meeting 10:4,5	85:10,17 86:1,5,7	missouri 4:5	37:20,21 104:7
market 45:21 46:2	meetings 83:8	86:16,18,20,22,23	mistake 25:5	105:20 106:19,23
46:11 63:6,11	memorial 3:7 47:19	87:3,7,23 88:3,8	moderate 68:3,8,19	114:12 122:22
99:4,8,9,16 105:1	47:19,21	89:12,19,21,24	moderaterisk 66:4	129:7
122:5 123:6	memory 44:11 85:6	90:2,3 92:12,15	moment 100:5	needing 10:8
marketing 131:22	85:8	93:11 94:4,5,12	month 47:2 49:12	needs 123:21
132:8,15,19 133:5	mention 33:15	94:13,15,23 95:9	morbid 100:10,14	131:16
133:7	40:20 96:22	97:19,21,24 98:2	100:19	never 20:4 23:21
marlex 90:2	mentioned 14:17	98:4,6,10,10,16	morrow 2:22	24:1,2 43:14,18
mary 1:15	16:6	98:18,20 99:10,11	move 13:13 63:1	43:19 49:1 67:18
	mesh 6:16,19 11:8	99:15,16,17,24	69:18 82:18 95:22	68:5 83:8 90:19

91:21 95:13 99:4 104:3,6 new 16:15 35:15 75:24 91:8 98:16 news 6:18 nice 34:7 nicely 11:12 nomenclatures 31:5 nonissue 78:3 nonmesh 58:24 nonresponsive 84:5 notary 136:23 137:4 noted 136:10 notice 6:3 7:20,23 9:16 56:5 notification 54:11 54:19 55:13 56:4 56:8 57:10 60:1 november 18:18 20:21 nuances 36:20 nudge 34:8 number 7:23 16:6 20:23 26:10 49:12 68:2 74:14 75:10 81:3 87:9,10,14 88:5,10,13,16,17 91:15 92:9,13 numbered 3:4 numbers 9:7 numerous 91:4,10 92:10 132:12	82:18 83:12,21 84:12 87:13 94:16 98:24 99:12,18 100:1 107:17 110:7 111:3 112:11 113:14 114:2,14 117:4,9 117:10 119:20 121:11 122:21 123:14 124:13 127:9 128:22 130:4,24 131:17 131:24 132:9,23 133:9,14 objection 9:22 10:6 23:3 obstruction 62:22 100:22 obviously 18:1 50:2 68:1 occasionally 27:24 occasions 26:22 occur 38:24 78:16 103:4 104:18 109:2 110:5 117:1 117:16 120:12,17 occurred 47:3 51:8 115:3 occurs 103:21 117:2 october 59:24 offer 46:10 69:23 87:5 93:13 96:18 100:10 106:13 offered 123:17 offering 77:15 119:12 office 137:16 officially 26:4 28:20 oh 12:7 14:19 18:13 20:20 22:24 25:7 33:4 71:9 74:24 102:9 104:12,14 124:21 okay 8:20 9:6,19	13:13 14:8 18:3 18:13,14,19 19:9 20:9,20 21:15 26:2 27:15 28:19 29:12 30:9 31:8 31:10,21 33:14 35:17,20 37:2,6 40:18 42:16 44:12 47:20 50:8 51:16 63:13 69:17 73:1 91:3 95:21,24 101:3 102:9 104:14,16 113:6,8 113:19 118:17 122:16 123:22 125:4 127:13 128:7,8 129:13,17 133:17 olsen 1:15 once 50:17 125:11 operations 111:14 opinion 55:6 64:15 69:22 70:23 71:3 74:16 75:6,12 76:1,6,17,19 77:15,23 78:5 87:4 89:19 93:13 96:18 100:10 101:8 106:13 115:22 119:12 123:3 131:7 opinions 10:19,22 10:24 11:12 13:19 16:4,19 17:7,15 17:17,19,23 18:7 18:8 46:10 65:16 67:7 77:15 84:2 114:17 115:8 opposed 11:1 93:23 oral 1:12 3:1 order 45:1,8 53:11 53:18 66:2 74:15 77:7 103:11 105:8 orders 83:9 organ 6:16,19 17:1 17:2,9 21:4 23:11	27:20,24 29:17 54:24 56:16 58:9 58:23 59:1 61:13 61:15 62:2,4,15 64:10,11,21 65:21 66:9 68:16,17 77:14 90:10,21 99:9 119:9,18,23 120:3,9,14,19,22 121:4,8,14,20 122:4 128:10,15 128:20 oriented 86:12,18 outcomes 63:15 64:4,11,16 outlier 83:2,5,11,18 84:8 outline 107:14 outside 53:7 overall 81:5,23 override 133:8	particular 10:23 111:9 129:8 131:20 parties 137:14 party 137:12 pass 38:24 passed 103:24 passes 38:15,20 39:2 patient 8:9 30:10 35:7 36:12,17 37:17,24 43:8 51:21 52:7 56:17 56:19 64:22 71:1 75:5 76:4,22 77:8 80:9 84:14,17 86:24 102:3,18,22 103:3,11 109:12 113:24 114:4 patients 27:17 29:1 32:13 36:23,23 38:5,6,9 50:14,15 50:19,20,20,23 51:11,12,15 52:10 56:4,7,15 58:9,16 58:17 70:8,8 77:20 87:11,15 105:16,22 129:24 130:3,8,20,23 paula 1:11 pause 132:14 pd 88:7 peerreviewed 23:22 24:2 pelvic 1:4 6:16,19 17:1,2,9 21:4 23:11 27:20,24 29:17 54:24 56:16 58:9,23 59:1,11 59:13 60:10 61:13 61:15 62:2,4,15 64:10,11,21 65:21 66:9 68:16,17 77:14 81:17 87:3 87:8,20 88:3,8,12 88:15 89:19 90:10
O object 13:13 17:21 22:12,13 23:19 25:3,6,21 35:11 36:3,18 39:17 44:20 45:17,22 46:3,12 52:8,18 53:2 56:20 58:15 60:5,14 63:1 64:6 64:14 71:13 73:11 77:17 78:18 79:24			P p 3:5,5 4:1,1 134:2 page 5:2 6:2 25:1,5 25:16 55:15 57:8 61:20 69:18 87:2 96:11 100:7 104:10 135:5 pages 136:5 pain 58:19 60:9 112:21 116:3,9 118:3,15 119:24 121:15 painful 116:13,24 117:18,21,23 118:6,9,24 paper 63:15 paragraph 55:18 59:19 66:1 68:12 parentheses 57:14 57:16 parenthesis 59:21 parkway 4:10 part 35:9,9,12 75:13	

90:11,21,22 99:9 111:13 112:15,16 112:17,21 116:3,8 117:20,20 119:9 119:18,23 120:1,3 120:5,9,14,19,22 121:4,8,14,15,16 121:20 122:4,12 122:15,17 128:10 128:15,20 pelvis 35:10 72:18 124:11 127:7,23 128:19 penetrated 118:21 penny 2:14 people 26:15 112:12 percent 55:9 71:9,9 72:11 73:2,13,24 74:4,9,10 80:11 80:18,24 81:2,3,6 81:24 82:9,15,17 84:15 88:20,21 94:14 95:4 105:11 105:13 106:2 percentage 72:22 perfect 107:9,9 perfectly 115:10 131:5 perform 35:2 performed 37:8 87:10 103:2 performing 37:11 period 27:6 37:7 47:6,13 48:12 51:7 103:18 peripheral 17:23 permanent 115:4 peroxides 79:21,22 80:2,6 person 48:23 117:23 personal 82:4 perspective 38:21 52:4 phrased 67:12	physically 118:5,9 118:14,20 physician 43:9 52:14 55:3 56:13 56:14,15,19 111:22,23,24 112:5,9 113:1,2 113:11,12,23 physicians 23:18 26:11 39:10 41:6 41:11 42:1 51:14 52:20 126:21 131:2 picturing 39:20 126:6 place 95:1,5,14 placed 48:15 61:12 61:17 62:1,21 86:19 95:18 103:16 104:1 placeholder 6:11 9:10 placement 6:16 placing 61:24 plaintiffs 3:3 4:3 10:3 96:12 please 20:7 69:15 116:21 130:12 plication 58:21 plus 31:6 33:16 50:6,9,15,17,20 51:1,3 54:18 98:9 98:11,15,17,19,23 99:4 115:20 point 19:7 29:23 30:1 34:8 45:3 57:12 58:6 59:20 61:23 62:1 63:12 64:24 99:8 points 11:11 poking 86:14 polymer 70:2,6,10 polymers 70:4,7 polypropylene 77:12,14,23 78:6 78:7,13,15,17,24	79:12,16 80:3,7 85:10 86:8 87:23 poor 94:20 112:21 pop 17:17 55:21 59:22 pores 61:8,8 portions 27:11 possession 8:6 possible 112:4,14 posterior 57:16,23 58:8,17,20,20 101:18 125:2,5,9 125:22 126:2,3 127:12 potential 38:21 59:10 94:8,9 96:2 96:4,7 103:4 111:15,20 112:6 112:16 114:21 115:1 potentially 43:6 78:9 102:4,19,23 103:9 107:3 128:3 practice 24:7 26:20 43:20 48:20 53:21 54:6 70:12 107:19 practicing 43:16 pramudji 1:13 3:1 5:5 6:4,5,7 7:1,5 7:20 15:11 23:5 40:3 97:11 136:14 137:6 precaution 132:7 132:18 prefer 36:5 prefers 118:23 premarket 69:13 preparation 8:9 prepare 19:4 prepared 40:14 preparing 20:23 107:11,15 preproliferation 30:8 prerogative 43:9 54:21 prescribed 103:18	103:24 present 4:13 58:24 79:22,23 pretty 12:7,13 19:11 80:19,20 98:14 previous 21:13 79:5 previously 58:1 59:21 124:12 127:7,23 128:4,20 price 31:22,24 primarily 34:24 primary 63:24 principle 11:24 prior 7:21 8:12 18:20 26:17 27:10 35:4 92:1 104:7 priority 133:12,15 probably 9:1,3 21:1,9 27:9 29:3 29:22 30:7 31:21 52:10 76:10 83:15 124:23 125:2,10 129:12 problem 95:9 problems 53:6 71:5 procedure 3:9 23:16 35:3 36:9 56:16 92:16,20 93:1 100:19,20 102:5,20,24 103:2 procedures 32:14 58:10 proceed 40:5 97:13 103:13 proceedings 137:10 process 7:13 28:12 produce 28:14 produced 3:2 8:12 19:10 21:17 92:5 producing 10:7 28:10,11 product 22:4 23:7 29:8 30:20,22 31:4 35:19,21,23	41:5,11,15,17,21 41:22 42:1,5,13 46:5,16 48:1,18 48:21 49:2,18 50:3 53:11,13 63:3,9 64:1 85:22 98:16 104:22 106:16 108:13 132:20 133:1 products 1:4 10:24 11:2,4,11,23 15:20 17:2,3,9,10 17:17 18:1 21:5 22:7 48:4 49:12 49:13 52:1 77:15 108:7,9 119:9,11 119:13,18,23 120:3,9,14,16,19 120:23 121:5,14 121:20 122:4 prof 39:13 professional 40:22 41:1,9 43:4 professionals 114:9 114:10 122:24 131:3 profile 11:7,16 12:21 project 104:21 projection 49:10 prolapse 6:16,20 17:2,2,9 21:4 22:11 23:11,17 27:12,20,24 29:17 32:17 35:9 38:9 39:11 50:23 54:24 56:16 58:10,23 59:1 61:13,15 62:2,4,15 64:10 64:12,21 65:21 66:9 68:16,17 72:2,8,20 77:14 90:10,21 99:9 119:9,18,23 120:3 120:9,14,19,23 121:5,9,14,20
---	--	---	---	---

122:4 128:10,16 128:21 129:22 130:18 prolene 31:4,12,15 31:20,23 41:21,24 53:21,23 54:1,3 61:3,10 69:22 70:14,18 76:14 79:16 89:6,21 93:11 128:12,12 128:17,18 prolift 10:18,20 12:4,11,20 13:2,7 15:16 16:19 17:4 17:20 18:12 29:24 30:2,4 31:6 32:20 33:15 36:21 37:8 37:16,22 38:4,13 38:22 39:15 49:16 49:22,23 50:6,8 50:13,15,17,19,20 50:22 51:1,3,5,20 54:17,18 66:17,23 67:19 68:7 70:14 70:19 72:7 80:16 80:24 81:6,24 82:9,14 84:14 85:1 88:1 91:6,12 93:5 98:11,15,17 98:22,23 106:8 111:21 112:7,24 113:10 114:1,18 115:18,20 119:10 124:10,10,20,21 124:23 125:3,3,4 125:8,9,12,16,22 126:1,2,4 127:5,6 127:7,19,21,22 128:2 properly 86:18,19 95:18 propounded 136:8 pros 121:2 prosima 6:14 7:7 10:18,20 11:6,15 11:19,20 12:1,11	12:13,15 13:3,8 15:16 16:19 17:4 18:6,9,16,20 22:4 23:13,15 24:6,13 24:19,21 26:3,7 26:16,16 33:3,4 34:13,17 36:13,20 37:11,16,18,23 38:14,20 39:4,6 40:9,12 41:5 42:5 42:13 45:2,8,14 45:16,21 46:1,11 46:15,19,23 47:8 47:13,14,24 48:6 48:10,14,18 49:6 50:13 51:19 52:2 52:7 54:10,15 63:3,15,18,24 66:14 67:19 68:7 70:15,19 71:8,24 72:14,24 73:4,8 73:17,21 74:2,11 80:10,17 85:1 88:1 91:7,12 92:19,24 93:5 98:9,19,22 99:3 100:8,17,20,23 101:8,10,11,14,18 102:1 103:16 105:8,12 106:4,14 106:20,24 108:15 111:2,21 112:7,24 113:10 114:1,18 115:14 119:10 123:6,12 129:8,21 130:16 protegen 104:21,21 105:1,5 proven 52:12 provide 20:11 provided 15:24 41:10 124:10 127:22 128:12,19 provides 56:24 57:16 58:13 127:6 provisions 3:10	prudent 112:8 113:2 ps 10:21 11:3,8,16 12:2,3,15,22 13:2 13:8 15:16 16:20 17:4 18:6,9 20:16 22:7 23:7 26:19 26:24 27:1,3,7 29:21 31:1,15,23 32:4,7 41:15,17 42:13 43:24 44:4 44:8 53:10,18 66:20 67:1,7,19 68:7 69:1,4,11 74:11,17 76:2,7 76:20 84:24 87:3 89:12 90:11,22 91:6,11 92:12,15 93:4,6 96:16 97:3 97:18 98:10,17 99:11,17,24 100:4 106:11 108:18,21 114:19 115:2,16 119:11 123:17 124:18 125:6,15 125:24 126:22 public 54:10,19 55:13 56:4,8 57:9 60:1 136:23 137:4 publications 8:8 22:1,3,6,9,15 23:6 23:9 published 23:21 24:2 pubmed 89:1,2 pulled 61:9 purposes 110:4 119:7 pursuant 3:9 push 86:1 pushing 86:5 put 39:19 42:15 50:16 86:21 110:16 115:9 122:20 124:11 127:6,22 128:19	129:9 131:2,13,16 132:21 133:4 putting 114:22 129:20 130:16 pvsdf 87:21 88:8 <hr/> Q <hr/> quality 89:10,11 question 7:14,15 11:13 16:15 18:6 18:10 20:14 22:14 22:18 34:2 35:13 37:7 40:14 43:19 49:16,22 54:13 58:3,21 59:4,7 62:24 63:7 64:9 65:12 69:15 71:14 71:14,20 72:12,21 73:16,19 74:20 75:21,24 77:9 78:5 87:12 89:8 89:24 90:7 91:1,8 95:20 99:7 102:13 113:17,20,21 115:11,16,18,20 117:6,12 119:13 122:18,18 123:16 128:7 129:2,4 130:7,10,13 131:8 questions 7:4 14:22 22:14 72:6 107:6 119:7,8 129:12,14 133:19 136:7 quick 97:5,8 quijano 2:5 quite 87:24 quote 76:9 88:17 <hr/> R <hr/> r 1:4 4:1 135:2,2 ran 49:20 randomized 14:1 87:15 91:4,10 92:8,14,18,22 range 73:14 80:19 80:21,24 81:2,7	111:5 rare 54:24 55:1,2,4 55:8,21 56:10,12 56:18 103:7,8 rate 26:2 62:20,21 74:8,9 80:24 82:4 82:8,14,16 94:14 95:4 105:9,11,12 rates 11:22 12:1,12 12:14 61:14,16,19 62:3,9,11,14 70:24 71:1,7,22 71:23 72:7,14,23 73:3,7,17,20 74:1 75:4,4,10 76:3,4 80:10,15 81:6,11 81:23 82:20,23 84:14,17 105:2,4 105:7 reach 74:14,15 reached 10:20 reaction 85:19,23 85:24 86:1,4 read 55:17 57:12 59:7 65:18 107:20 107:23,23 108:1 108:24 109:9,18 116:17,18 136:4 reading 34:5 reads 62:1 ready 40:4 97:12 real 97:7 129:15 realistically 103:6 really 13:11 28:4 33:12 34:1,23 35:4 36:23 62:17 114:15 128:23 132:18 realtime 130:9 reask 22:18 72:21 84:5 119:6 130:10 reason 10:23 39:2 75:16 132:15 135:7,9,11,13,15 135:16,18,20,22 135:24
--	--	---	--	---

reasonable 54:9,14 54:16 111:24 112:8,15 113:2,5 113:12,22 114:4 reasons 94:21 131:22 132:8,15 133:5 recall 19:6 27:6 29:7,15 31:17,20 33:9 42:11 43:7 43:20 44:7,12 45:4,6,11,13,19 45:23 46:7,22 47:1,2,5,12 48:11 48:14 51:7 53:15 53:16 67:21 85:3 85:7 92:17 93:8 105:6 108:14,20 108:23 122:6 recite 45:10 reclassify 66:3,12 reconsider 74:15 75:11 reconstructive 87:4 87:8,20 88:4,8,12 88:15 89:20 90:11 90:23 record 3:10 34:7 39:24 40:4 63:2 97:12 134:1 records 8:10 19:8 83:8 rectal 101:19 rectocele 37:19 38:1 40:10 recurred 72:2 recurrence 71:1 75:4 76:3 recurrent 72:16,19 recurring 72:8 reduced 137:8 refer 21:20 69:19 91:18 119:9 referenced 6:7 references 26:1 referring 17:3	18:22 27:2 51:13 58:1 69:1 119:10 refresh 44:10 85:5 refreshing 85:7 regard 45:1 53:12 55:24 115:14 117:7 regarding 7:7 8:15 10:17,20 17:19 18:8,16 20:16 44:18 67:7 70:23 83:9 106:23 109:10 regards 68:8 89:18 registration 137:21 regular 137:12,12 regulations 114:11 regulatory 52:4 114:9 reinforce 57:5 related 71:5 129:24 130:19 relates 1:6 55:4 70:11 release 6:18 63:11 reliable 96:14 97:2 97:17 115:10 reliance 6:7 14:12 14:22 15:15 16:24 17:8,12 91:20,22 relied 16:3,18 65:16 reluctant 27:18 rely 17:15,18 18:7 75:3 76:15 109:7 relying 76:5,19 remains 64:20 remember 10:1 19:7 24:15 28:23 48:16 51:9 100:5 107:7 125:18 remind 33:22 remote 121:22 removal 103:22 remove 76:11 removed 45:21	46:1,11 76:24 104:7 105:1 reoperation 70:24 71:7,19,22,23 72:7,14,23 73:3,7 73:17,20 74:1,8,9 75:3,10 76:3 80:15 rep 28:17 108:11 repair 1:4 6:19 27:13,20,24 29:17 30:11,12 54:1,23 55:21 56:23 57:3 57:4,14,15,16 58:17,21,23 59:1 59:22 61:13 62:2 63:4 64:10,20 65:21 66:8 68:13 68:15,17 90:10,21 90:21 99:9 128:10 128:15,21 repaired 71:11 repairs 34:14,16 64:3,9 82:17 117:3 118:12 repeat 69:15 rephrase 7:15 102:12,13,15 replace 79:4 report 6:5,8 10:17 10:19 11:1 13:15 13:19,22,23 15:16 15:17 17:9,10 19:4 20:11,19,24 21:4,8,11 22:7,9 22:15 24:18,21 25:17 42:13 69:19 87:2 91:3,9 93:9 96:11,21 100:7 104:10 reported 3:6 59:23 105:4 reporter 4:14 9:17 20:6 33:24 34:9 137:4 reporters 5:9	reports 8:15,18,23 9:2,13,14 15:20 17:12 19:21 59:24 representative 108:11 represented 21:19 21:24 requests 7:24 8:1 require 120:24 required 41:4 46:6 114:10 121:6 requirement 65:20 requirements 6:19 research 46:6 reserved 5:8 134:3 residency 111:15 112:13 residual 67:18,22 68:2 resolve 121:21 resources 46:6 respect 82:2 83:22 respectfully 60:6 response 24:24 45:7,12,14 53:17 57:11 59:6 64:7 116:15 responsive 8:1 restart 43:18 restate 116:16 restorelle 35:22,22 36:6,10 97:19 result 50:18 62:3,8 62:9,13,16 120:15 results 50:18 51:11 61:13 99:2 resume 14:17 retropublic 15:21 review 14:2 44:15 65:11 89:9,16 reviewed 7:21 16:3 16:18 40:13 44:8 44:13 65:15 110:20 reviewing 21:11 rhynchart 2:14	riddell 1:12 ridgeland 4:10 right 7:15 15:21 18:22,24 19:13,18 20:2 24:11 26:17 29:7,19,21 31:17 32:9 37:13 39:20 42:3,17 58:17 70:10 75:7,8 78:7 78:10,11 79:12,23 80:8 81:16 82:9 92:17 94:22 95:2 96:22 101:9 105:6 108:23 119:1,2 127:17 129:13,14 132:24 133:24 rigorous 44:18 rise 75:11 risk 59:2,9,13,22 62:22 64:18 67:11 67:11,15,15,18,22 68:2,3,3,3,19 100:17,21,24 101:6,7,7,15,16 101:18,19,22,22 101:24 111:20 112:6,24 113:10 113:24 114:6 115:1,4 119:21 121:22 122:1 133:2,4 risks 6:20 11:20,21 13:7,8 58:24 59:10 64:4,12,17 65:22 106:15 109:1,5,8,12,17 109:20,21 110:4,8 110:13 115:12 119:4,17,23 120:2 120:9,13,18 121:9 121:14,20 122:2,3 122:11,12,14,14 122:17,19,20 123:4 133:1 road 3:8 roll 133:20
--	--	--	---	---

rule 19:20 rules 3:9 <hr/> S <hr/> s 1:5 4:1 sacro 35:16 sacrocolpopexy 34:21 35:7 36:8 61:18 62:19 64:24 100:9,16 101:5 safe 44:23 52:12 63:22 safer 96:12 97:17 safety 6:17,20 11:7 11:16 12:21 17:19 17:24 18:4,9 38:21 44:19 63:5 63:9 65:21 sale 28:22 46:24 47:9,10 sales 28:17 108:11 132:20 sampling 14:5 sandra 1:18 satisfaction 71:2 75:5 76:4,23 80:9 84:14,17 saw 15:8 50:18 51:11 57:7 63:23 83:14 saying 22:22 58:3 62:9 71:16 75:9 95:16,16 118:3 says 40:15 55:18 59:20 62:8 66:1 68:12 132:19 scale 121:21 scar 59:18 60:8,18 60:24 61:6,10 116:7,12,23 117:13 scared 32:14 118:13 scarring 59:16 60:16 117:20 school 93:18	science 11:3 70:6 scientific 29:3,4 59:23 96:15 97:2 97:18 score 67:22 68:2 scores 67:11,15 screen 116:19 seal 137:16 search 89:1 searches 89:3 second 39:24 40:18 55:15 59:19 65:11 66:2 see 15:9 24:14 37:4 38:20 39:19 40:15 42:15 51:13,17,18 53:4 55:22 57:8 57:19 60:8 62:1 62:10 65:23 66:6 68:21 70:15 71:5 72:21 77:2 89:21 94:24 95:1,1,10 99:2 seeing 62:19 105:11 seen 44:24 45:7 53:11 62:18 65:12 67:18 68:5 82:10 83:8,13 95:14,17 104:3,6 110:22 selection 50:12,14 sell 46:5 67:16 69:11 selling 48:1 49:18 semantics 61:1 send 9:17 sense 11:4 19:17 30:4 75:19 87:12 sent 8:12 sentence 66:2 separate 14:20 separately 91:21 119:15 separating 11:1 serious 6:15 55:19 56:17 set 137:9	seven 84:21 85:2,4 severe 38:9 50:23 115:3 116:3,8 severity 107:3 sewing 76:15 94:19 sexual 116:14,24 117:7,14,17,19,24 118:8 sharon 1:14 2:7 sharp 86:16,20 sheet 124:18,19 125:6 126:22 136:10 shelf 48:17 49:12 shelves 47:24 49:18 sherry 1:21 shively 2:19 short 40:4 97:12 shortening 60:9 shorthand 3:7 137:3 shortly 24:14,16 show 63:9 75:16 76:9 81:1 82:10 123:20 showing 44:22 shown 81:9,9 shows 63:22 94:14 95:3 shrink 60:13,15,23 shrinkage 59:21 60:4 116:2 shrinking 61:2 shrinks 60:17,19 shrunk 61:4,5,9 61:10 sic 17:18 93:23 side 76:8 95:7,10 sides 95:17 125:14 sidetracked 29:10 signature 5:8 134:3 significant 13:11 38:17 109:12 similar 12:8,13,18 61:16,19 62:11,20 64:4,10,17 99:2	99:19 125:11 single 11:1 124:18 sit 39:9 44:3,7,12 45:11,13 46:1 74:7 83:14 90:16 93:21 99:14 110:11 sites 120:20 sitting 30:24 31:11 42:11 43:23 44:7 45:4 53:15 67:21 69:3 88:17 122:8 situation 30:16 112:3,5 situations 43:5 52:19 118:12 132:5,21 133:7 six 93:2 size 125:15,17 sizes 32:3 123:16 slight 39:3 58:18 slightly 12:12,23,23 39:3 99:19 slings 17:16 18:7 small 71:10 81:10 101:16,19 105:22 118:16 smaller 101:22,24 smith 1:20 smoking 94:20 snow 4:9 8:13 16:1 19:1 soft 31:4,12,15,20 31:23 41:21,24 54:1 69:22 70:14 70:18 128:12,12 128:17,18 sold 41:5 46:20 47:15 sonoma 81:18 sorry 12:10 15:6 18:5,10 20:8 48:24,24 88:16 90:7 100:2 104:13 133:18 sort 76:8 89:13	112:2 123:23 sorts 109:24 sounds 24:11 southern 1:1 speaking 23:3 58:16 specific 36:14 38:5 42:8 110:1 122:18 129:23,24 130:19 130:20 specifically 20:18 22:4,7,10 23:7,10 43:1 46:22 96:21 specifics 44:16 132:16 spent 20:23 21:8,11 square 123:12 125:7 126:15,23 squared 100:4 st 47:21 stacked 16:10 stand 42:18 standard 51:23 52:15 53:7,9,20 53:22,24 54:3 64:20,23 110:12 112:9 standardized 128:24 129:5 standards 106:18 106:22 start 16:13 35:2 77:10 116:1 started 20:20 34:23 35:5 50:19 starting 75:15 state 3:6 19:19 39:12 69:21 70:24 76:2 87:2 91:3 93:9 94:18 96:11 100:7,8 102:1 137:1,4 stated 3:10 32:6 85:20 122:13 137:5 statement 57:9,21
--	---	--	--	--

58:4 59:5 62:7,13 63:14,17,19,20 102:21 104:5 115:6 states 1:1 39:15 40:9 41:18 42:2 stockpile 49:6 stone 2:17 stop 27:15 28:8,11 28:20 54:9,14,17 stopped 28:9 32:6 46:16 48:1 49:18 82:22 stopping 28:13 story 50:7 straight 72:22 strengthens 6:18 65:19,19 strictly 53:5 strike 13:14 16:13 17:7,16 20:13 23:14 24:1 29:13 35:14 38:17 41:8 45:12 47:6 54:15 56:14 61:11 63:1 64:2 66:24 67:12 69:16 70:22 71:22 73:18 75:22 77:8 78:14 82:19 89:7 91:7 94:1,8 95:22 108:8 110:2 113:7 115:24 116:6,11 117:4 119:5 120:6 121:3,17 123:1 124:8 128:13 133:15 strings 17:18 strip 125:23 strong 44:22 strongly 69:24 studied 64:1 70:5 87:3,7,11,18,24 88:8,12,15 89:19 90:10,14,22 93:16 93:19 97:1 115:11 115:15	studies 14:2,3,5 26:11 44:18 45:15 57:5 61:18 62:18 76:9,11 80:14,20 80:22 81:1,1,9,10 81:11 82:8,10 84:18,19,20 85:3 85:9 87:10,11,14 87:15 88:2,7,11 88:14 89:3,11,12 89:13,21 91:5,11 91:19 92:11 93:3 93:6 study 45:16 82:11 82:14,21 83:24 84:22,23 85:3 94:13 95:3 97:18 97:24 98:2,4 stuff 29:11 subject 9:16 submit 69:12 subscribed 136:17 subset 38:6 substance 17:22 93:17,23 94:10 96:9 136:9 substitute 9:18 success 76:22 sufficient 106:15 106:17 suite 4:5,10 137:22 suited 37:18 sulcus 95:18 summit 81:17 superior 63:16 supplement 29:23 30:5,7 supplementation 124:15 support 17:24 30:3 37:19,20,21 38:2 38:12 50:24 57:14 63:15 69:21 70:23 74:16 76:1,2,6,7 76:19 103:17,22 103:23 104:7	123:8 supportive 75:16 supports 71:3,4 suppose 86:15 supposed 110:13 sure 7:16 14:23 19:11 25:19 44:10 44:15 45:3,9,18 46:13 52:4 54:12 58:2 67:17 72:12 78:4 79:14 83:14 85:15 87:1 90:13 93:18 99:1 108:17 114:11 surgeon 43:3 70:4 103:16 111:13 112:15 124:14 125:19 128:1 surgeons 68:13 110:10 122:12,17 122:23 123:7 133:2 surgery 36:6 57:1 57:17 58:14 59:1 59:11,14 61:15 62:4,15 76:15 79:17 87:4,8,20 88:4,9,12,15 89:20 90:12,23 102:3,18 103:5,13 109:6 111:17 112:17 117:20 120:1,5 121:16 122:15 128:24 133:3,3 surgical 6:16,19 23:14,16 43:11,14 43:19 54:22,23 55:7,20 56:18 61:24 65:20 66:8 66:12 68:12,15 109:5,15 120:10 120:24 133:3 surprised 112:20 112:21 surrounding 94:4	94:12 116:13,23 117:13 surrounds 61:7 survey 89:13 sustain 120:15 suture 30:11 62:20 82:16,20 94:22 95:2,8,8 103:20 sutures 34:14,17 79:16,16 switch 51:10 sworn 3:3 7:2,9 136:17 137:8 syndrome 119:24 synthetic 30:13,15 30:16 63:3 64:4 64:11 system 1:4 systematic 89:9,16 <hr/> T <hr/> t 135:2 tail 125:14 take 6:3 7:6,13 41:20 42:16 43:11 61:3 85:5 97:5 105:23 106:1 109:4,16 110:10 taken 3:3 129:7 137:12 talk 36:13,16,19 56:5 talked 39:5 42:5 50:12 79:15 talking 11:18 12:3 12:5,11 52:22,23 53:4,24 82:5 85:13 95:6,6 97:15 101:1 104:12 112:2,3 tamara 3:5 4:14 137:3,19 tasting 81:20 taught 39:13 taylor 2:20 technique 22:10	23:11 72:20 94:20 112:18 128:11,16 128:18 129:5 techniques 23:17 technologies 137:21 tell 7:9 10:16 14:11 19:17 21:20 24:12 56:7 58:12 74:23 81:4 93:21 109:7 telling 75:9 tells 39:10 56:16 ten 55:9 71:9 73:1 73:13,24 74:9,10 81:2 124:5 125:17 125:18,23,23 126:7,7,12,12 tenbyten 126:22 tend 96:18 terms 13:21 35:6 63:4 89:3 106:19 125:7 terri 2:19 testified 7:2 104:20 104:24 testify 137:8 testimony 59:12 95:13 112:23 113:9 testing 70:13 texas 3:6,8 19:19 20:1 137:1,5,19 137:21,23 thank 18:14 22:18 102:16 thats 10:9 13:5,12 14:4 15:22 19:18 19:24 23:2,24 24:5,11 25:7,13 25:13,19 26:6,18 27:14 32:10 33:21 35:22 36:11 37:10 37:14 38:16 42:3 43:8,22 44:14 46:18 49:21 50:11 53:6,7,24 54:20
---	---	---	--	---

56:2 63:7,23 65:4 67:24 68:10 70:18 70:19 71:15 74:5 74:24 75:13,14,14 79:7,8 80:19,20 81:8,8 83:1,18 84:1,9,11 91:14 93:12 94:23 95:9 96:10,17 97:21,23 99:23 100:2 103:14 104:10 105:3,24 107:14 108:2 114:16 123:3,10,19 124:2 125:6 127:1 131:2 theory 13:12 76:16 theres 7:23 16:9,9 17:12 21:24 31:22 32:12 50:2 57:4 72:19 74:12,21,23 75:9 77:19,22 78:2 84:5 85:21 86:3,6 87:22 93:2 94:21 99:7 101:5 101:9 105:23 109:5,14 111:4,6 121:22 125:6,21 132:24 theyll 9:18 theyre 11:21 12:7,7 12:13 13:11 14:2 18:1 28:12 31:18 36:1 52:1 54:20 55:8 61:4 62:8,10 80:11,11 99:19 103:5 110:19 113:15,21 114:20 115:7 128:2 131:9 132:11,12 theyve 28:9,9 62:16 thing 126:20 133:22 things 43:5 52:21 52:22 78:16 79:10 109:24 115:8 131:9 132:11	think 11:10 17:24 19:15,20,23 25:22 28:12,12,23 29:1 29:6 32:7 33:14 36:22 41:16 42:5 42:7,14 44:21 49:11 52:12 53:5 53:8,8 55:7 57:2 62:9,17,24 63:5 63:21 64:15 67:5 67:12,20 69:7 71:14,18 73:15 75:20 76:10 77:18 78:9 82:2,3,5 83:6 85:14,21 86:11 91:7 95:3,20 99:19 103:3 105:10,18 106:6 107:1 110:8,10 111:13 112:1,12 112:14,15,20 113:4,5 114:20,21 114:22 115:9,23 117:15 122:12,22 123:15 124:1,5,14 124:23 125:1,10 125:17,17 129:11 130:6 131:4,4,5,6 132:18 thinking 11:22 22:15 124:24 third 57:12 thought 12:10 37:21 114:12,17 132:7 three 10:24 21:4 46:17 55:18 84:17 106:6 119:7,11,13 119:14 123:24 throwing 9:7 thumb 8:6 tightening 60:9 time 15:6,19 18:12 20:7 21:21 23:2 27:6 29:2,15,22 30:6 33:10 34:8,8	34:12 37:7,15 42:17 46:15,16,20 47:7,13 48:12 50:9 51:3,7 62:18 76:13 84:16 107:24 108:1 124:24 137:11 times 26:23 27:5 33:12 34:5 36:4 39:2 107:7 119:7 tina 2:22 tissue 27:13 30:11 34:14,16 60:8,24 61:6,10 63:4 64:3 64:9,20 82:17 85:18 86:1,4,6,15 90:10,20 93:16,20 93:22 94:3,11,12 94:18,19 96:3,4,8 96:8 112:18 117:2 118:12 titled 65:19 today 7:6,21 8:1,4 8:14 10:10 16:13 16:18 30:24 31:12 39:9 42:11 43:23 44:3,8,12 45:4,11 45:13 46:1 51:20 51:24 52:3 67:21 69:3,12 74:7 83:14 88:18 90:17 93:21 99:10,15 110:11 122:8 123:4 told 45:20 46:8 47:8 58:16,17 81:22 83:10 108:6 108:12 top 25:5 57:14 92:9 123:13 126:5 total 29:24 30:4 124:21,23 125:3,7 126:11 127:19,21 127:21 128:2 track 41:1 traditional 53:20	53:22 54:3 57:1,4 57:17 58:14,20,24 89:21 98:22 trained 43:3 131:3 training 109:5,15 112:13 transabdominal 61:17 transcript 34:5 137:10 transcription 136:6 transition 50:19 transvaginal 6:16 6:19 22:10 23:10 27:17 29:2,6 35:1 44:1,4 54:23 55:21 56:23 57:3 57:13 58:23 59:22 61:15 62:4,14 65:20 68:17 69:5 69:11 128:11,16 128:18 transvaginally 61:17 93:7 treat 73:21 74:2 120:11 treated 24:1 treating 24:3 27:12 treatment 22:11 23:11,14,16 32:17 35:6,10 64:21 72:24 73:4,8,22 73:23 74:2,8 105:20 113:12,23 114:5 trial 26:16 63:19,24 91:18,23 92:2 trials 14:2 26:11 91:4,10 92:8,15 92:19,23 tried 24:17 33:12 34:21 36:4 45:15 trim 125:12 126:19 126:20,23 127:1 trocac 38:15,19,24 39:1	trocars 13:2,3,6 101:4 true 75:18 137:5,10 truth 7:10 137:8 try 7:15 13:24 14:4 99:1 107:4 turn 55:15 57:8 61:20 tv 15:17,20,21 17:10,18 18:8 tv 15:17,21 17:10 twice 105:18 two 22:13,14 39:11 55:17 84:19 85:9 128:3 129:11,14 typewriting 137:9 137:9 typical 64:21 typically 107:20 126:23,23 127:1,5 <hr/> U <hr/> u 1:5 uhhuh 9:9,12,15 10:15 11:14 12:17 14:10 15:12,14 16:8,11,14,21 25:18 32:24 33:21 34:3 53:1 55:14 55:16 58:11 60:20 60:22 90:4,18 132:4 ultimately 10:5 47:16 99:4 ultrapro 87:21 88:11 96:22 98:10 98:20 un 118:4 unable 117:17,23 118:1,8,9,14,21 unacceptably 105:2,9,14 106:5 uncomfortable 29:1 54:20 105:10 undergo 94:11 undergrad 70:5
--	--	--	--	---

understand 7:7,9 7:14 35:12 36:24 43:11 53:3 55:4 70:7 75:2 76:18 80:5	125:12 utilize 128:6 utilized 84:24	132:18 warnings 106:14 106:20,24 wary 27:17 wasnt 18:10 19:12 25:20 30:1 79:10 89:15 113:2,12 131:22	wine 81:20 withdraw 102:12 102:14 117:11 witness 3:2 19:15 19:18,24 20:3 22:24 33:23 34:3 71:15 90:6 97:9 133:17,20,23 137:6,7	130:9 wrongful 131:23 132:22 wrote 24:18,20 www 137:24
understanding 45:24 46:4,7 110:12	vagina 57:14,15 79:18,22 95:7,11 118:2,13,15	watch 129:16 water 39:24 wave 1:7 6:8 8:15 18:17 20:19 way 31:19 33:24 72:18,22 74:20 86:21 90:20 108:4 111:18 119:13 122:7 124:7,9 127:4,20 128:9,15 128:24 129:2 133:18	woman 33:1 115:4 120:14 128:4 129:21 130:17 womans 110:6 124:11 127:6,22 128:19 women 69:21 74:16 76:1,6 120:23 129:8 wondering 98:16 wont 96:1 word 55:4 63:1 123:1 133:15 words 113:3,4 work 8:15 34:1 36:5 112:9 114:7 worked 47:12 51:18 52:9 works 70:7 108:12 worse 89:11 wouldnt 31:18 86:5 105:13 112:5 127:18 wound 59:15,16,18 60:8,16,18,24 61:6 94:18,23 95:9 112:21 116:5 116:7,12,22 117:1 117:12 writing 13:21 107:11,15 writings 107:11 written 19:4 20:11 62:16 wrong 19:11 67:13 91:7 107:14 130:9	x 49:12
understood 90:7 unidentified 59:21 unintended 85:18 85:24 uninterested 118:1 118:4 unique 11:20,20,21 13:7 united 1:1 41:18 42:2 unquote 76:9 unwilling 118:1,4 update 6:15 55:19 updated 14:17 15:5 21:19,24 108:13 108:16,19,22 uphold 29:8,9 33:5 33:6,11 98:6 upwards 105:11 usda 6:15 use 26:19 27:11,23 28:2,5 29:3,5 30:22 32:16 33:8 35:23 36:2,15 37:4,17 42:1 43:2 43:3,5,9 44:1,5 48:5,6,10 49:9,19 50:4,8,21 52:20 64:5,12 68:19 69:5,12 72:20 76:14 88:24 91:22 93:4,6 107:21,24 110:5 111:1,5 115:14 126:19,21 126:23 uses 99:10 usual 48:20 usually 95:17	vaginal 36:16,19 60:9 103:17,22,23 104:6 123:8 various 13:16 115:13 vast 95:2 versa 34:18 versus 12:11 50:13 58:20 98:17 118:9 vessels 100:22 vice 34:17 view 34:16 viewpoint 44:17 vinson 3:6 4:14 137:3,19 virginia 1:1,17 vitae 6:9,12 23:7,10 vypro 31:8 87:21 88:3 96:22	wall 57:15,23 58:1 58:8 101:1,6,9 walltowall 32:12 want 14:17 15:7 32:15 34:6 39:23 42:16 59:7 63:10 63:11 69:20 96:1 103:12 116:16 130:10 133:4,10 133:11 wanted 69:10 warlick 2:10 warn 114:21 warning 47:5 131:20,21 132:6	wcllp 4:6 website 44:14 week 81:22 weeks 28:13 weight 99:10,16 100:3 wendy 2:4 went 21:11 122:4 123:4 west 1:1 westinhouston 3:7 weve 62:18 63:21 whats 7:18 10:14 14:8 21:15 37:7 40:11 55:11 65:8 84:22 whatsoever 110:12 whens 33:10 white 1:17 wide 111:4 widely 25:1,20 william 4:9,11 9:10 14:15 19:11 22:18 23:3 65:10 williams 2:16 wilson 2:1	y 35:24 36:1,1 yeah 15:4 19:22,24 21:1 22:19 25:11 25:13,14 33:4 34:11 39:22 71:18 73:14 77:1 79:14 80:20 81:8 84:4 90:6 97:9 102:11 102:14 104:15 106:3 113:17 116:20 124:1,1,1 124:2,2,5 125:10 126:2 127:13,14 129:18 130:14 132:19 133:23 year 18:21,21 47:2 69:7 79:6 84:17 108:22 years 33:9,13 43:15 43:17,20 46:17 49:13 70:4 84:17 84:19,21 85:2,4 108:7,9 youd 11:19 13:1 29:5 67:6 79:11 81:7 86:16 89:15 111:8 112:4 youll 9:17 102:12 youre 7:9 11:17,17 16:16 18:22 19:23 22:16 27:1 34:6 53:4 55:3 75:2,9 76:5,18 77:15 80:21 82:11 84:22 84:23 88:17 101:18 102:12

Christina Pramudji, M.D.

Page 155

104:16,20 109:3 111:13,13,14,17 112:2,3,18 115:22 118:3,17,19 119:11 youve 7:12 10:20 11:13 16:6,6,18 16:24 17:8 20:23 22:14 23:21 24:1 24:2,6,9 26:23 27:6 32:22 33:2 33:14,15 34:20 43:14,18,19 44:8 44:13 49:1 62:24 67:18 68:5 81:14 83:8 90:19 91:21 95:13,20,20 96:2 104:6,20 107:5,6 110:20 111:14 123:15	12cv00760 1:23 12cv00783 2:4 12cv00799 2:6 12cv00806 1:10 12cv00878 1:22 12cv00899 2:3 12cv00938 1:11 12cv00958 1:17 12cv00960 2:12 12cv01119 2:15 12cv01275 2:13 12cv01286 2:1 12cv01318 1:20 12md02327 1:3 136 5:8 138 5:9 1400 4:10 15 6:6 43:20 80:24 81:6,24 82:14,17 94:14 95:4 1950s 68:13 1970s 68:14 1990s 68:16	42:7 60:1 2009 25:23 26:4 37:12 2010 24:22 25:2,20 26:4 37:12 40:12 2011 27:9,15 29:22 34:24 35:4,5 54:10,18 55:12 81:17 2012 37:9 2013 44:8 58:10 2015 44:13 2016 1:14 3:5 65:22 137:16 20th 60:1 21 103:24 104:8 21day 103:18 22 6:9,12 23 1:14 23rd 3:4 25 3:5 88:20 105:13 134:2	5 5 6:10 9:8,18,20 100:7 50 21:2,3,7 88:20 522 44:24 45:7,14 45:16 46:7 53:11 53:18 83:9 56 6:15 5711 4:11	6 6 6:12 21:18,21,22 21:23 601 4:11 64112 4:5 66 6:18 690 137:21	7 7 6:13 40:7,11 41:4 701 4:6 75 24:9 84:15 77002 137:23 77024 3:8	8 8 5:6 6:3,15 55:10 55:12 65:2,3 80 80:11 816 4:6	9 9 6:18 65:1,2,5,6,8 68:11 90 80:11 84:15 910 137:22 945 3:8 948 4:11
Z							
0							
1	2	3					
1 1:7 3:5 6:3,8 7:17 7:19 8:15 20:19 10 6:10 1020 4:10 11 6:5 1100 4:6 12312016 137:20 12cv00276 2:10 12cv00277 1:8 12cv00335 1:19 12cv00368 2:7 12cv00376 2:21 12cv00378 2:22 12cv00379 2:19 12cv004001 2:24 12cv00470 1:16 12cv00483 2:9 12cv00511 2:16 12cv00547 1:13 12cv00554 1:14 12cv00652 2:18	2 1:3,8,10,11,13,14 1:16,17,19,20,22 1:23 2:1,3,4,6,7,9 2:10,12,13,15,16 2:18,19,21,22,24 6:5 10:12,14 13:16 37:18,24 39:7,16 40:10 20 3:5 21:9 72:11 73:1,13 74:4,9 80:18,24 81:6,24 82:9 94:14 95:4 123:23 136:19 200 1:7 2000 70:8 2002 27:8 41:16 68:18 69:1 2005 27:10 32:18 37:8 2007 26:8 2008 24:15 25:12	3 5:3 6:6 14:7,9 15:13 16:22 20:24 37:18 38:1 39:7 39:16 40:10 57:8 69:18 87:2 30 21:12 105:11 106:2 300 4:5 3015 137:19 39157 4:10 3s 38:10,10	4 4 3:5 6:9 21:14,16 61:20 96:11 123:23 134:2 40 25:5,16 41 6:13 25:1 104:10 440 137:22 4740 4:5 4s 38:9 4th 65:22				

Christina Pramudji, M.D.

Page 138

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.,) MASTER FILE NO.
PELVIC REPAIR SYSTEM) 2:12-MD-02327
PRODUCTS LIABILITY)
LITIGATION) JOSEPH R. GOODWIN
-----) U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO)
THE FOLLOWING CASES IN WAVE 1 OF MDL 200:)
Joy Essman)
Case No. 2:12-cv-00277)
)
Barbara A. Hill)
Case No. 2:12-cv-00806) ORAL DEPOSITION OF
) CHRISTINA PRAMUDJI, M.D.
Paula Kriz)
Case No. 2:12-cv-00938) MARCH 24, 2016
)
Brenda Riddell)
Case No. 2:12-cv-00547)
)
Sharon Carpenter)
Case No. 2:12-cv-00554)
)
Mary Jane Olsen)
Case No. 2:12-cv-00470)
)
Virginia White)
Case No. 2:12-cv-00958)
)
Sandra Wolfe)
Case No. 2:12-cv-00335)
)
Marie Smith (f/k/a Banks))
Case No. 2:12-cv-01318)
)
Sherry Fox)
Case No. 2:12-cv-00878)
)
Lois Durham)
Case No. 2:12-cv-00760)
)
Elizabeth Blynn Wilson)
Case No. 2:12-cv-01286)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 139</p> <p>1 Daphne Barker) Case No. 2:12-cv-00899) 2) 3 Wendy Hagans) Case No. 2:12-cv-00783) 4) 5 Maria Eugenia Quijano) Case No. 2:12-cv-00799) 6) 7 Sharon Boggs) Case No. 2:12-cv-00368) 8) 9 Robin Bridges) Case No. 2:12-cv-00651) 10) 11 Carey Cole) Case No. 2:12-cv-00483) 12) 13 Cathy Warlick) Case No. 2:12-cv-00276) 14) 15 Donna Amsden) Case No. 2:12-cv-00960) 16) 17 Heather Long) Case No. 2:12-cv-01275) 18) 19 Penny Rhynehart) Case No. 2:12-cv-01119) 20) 21 Nancy Jo Williams) Case No. 2:12-cv-00511) 22) 23 Maria Stone) Case No. 2:12-cv-00652) 24) Teri Key Shively) Case No. 2:12-cv-00379) Charlene Logan Taylor) Case No. 2:12-cv-00376) Tina Morrow) Case No. 2:12-cv-00378) Carol Jean Dimock) Case No. 2:12-cv-00401)</p>	<p style="text-align: right;">Page 141</p> <p>1 APPEARANCES: 2 WAGSTAFF & CARTMELL, LLP BY: ANDREW N. FAES, ESQUIRE 3 afaes@wcllp.com 4 4740 Grand Avenue, Suite 300 Kansas City, Missouri 64112 (816) 701-1100 5 Counsel for Plaintiffs 6 7 EDWARDS & DE LA CERDA, P.L.L.C. BY: PETER DE LA CERDA, ESQUIRE 8 peter@edwardsdelacerda.com (Via Speakerphone) 3031 Allen Street, Suite 100 9 Dallas, Texas 75204 (214) 550-5239 10 Counsel for Amsden Plaintiff 11 12 HERMAN, HERMAN & KATZ, LLC BY: MIKALIA M. KOTT, ESQUIRE 13 mkott@hklawfirm.com (Via Speakerphone) 820 O'Keefe Avenue 14 New Orleans, Louisiana 70113 (504) 581-4892 15 Counsel for Taylor and Shively Plaintiffs 16 17 THE POTTS LAW FIRM, LLP BY: STEPHEN R. RICKS, ESQUIRE 18 sricks@potts-law.com (Via Speakerphone) 19 100 Waugh Drive, Suite 350 Houston, Texas 77007 20 (713) 963-8881 Counsel for Carpenter Plaintiff 21 22 23 24</p>
<p style="text-align: right;">Page 140</p> <p>1 2 - - - 3 Thursday, March 24, 2016 4 - - - 5 Oral Deposition of CHRISTINA 6 PRAMUDJI, M.D., taken pursuant to notice, was 7 held at the Westin Houston, Memorial City, 8 945 Gessner Road, Houston, Texas, beginning 9 at 8:13 a.m., on the above date, before 10 Micheal A. Johnson, Registered Diplomat 11 Reporter, Certified Realtime Reporter, and 12 Notary Public for the State of Texas. 13 14 15 - - - 16 17 18 19 20 21 GOLKOW TECHNOLOGIES, INC. 22 877.370.3377 ph/917.591.5672 fax deps@golkow.com 23 24</p>	<p style="text-align: right;">Page 142</p> <p>1 APPEARANCES: 2 BUTLER SNOW LLP BY: WILLIAM M. GAGE, ESQUIRE 3 william.gage@butlersnow.com 4 1020 Highland Colony Parkway Suite 1400 5 Ridgeland, Mississippi 39157 (601) 948-5711 Counsel for Defendants 6 7 - - - 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>

Christina Pramudji, M.D.

Page 143				Page 145			
1	INDEX			1	PROCEEDINGS		
2	CHRISTINA PRAMUDJI, M.D.			2	CHRISTINA PRAMUDJI, M.D.		
3	March 24, 2016			3	having been first duly sworn,		
4	APPEARANCES	142		4	testified as follows:		
5				5	EXAMINATION		
6	EXAMINATION OF CHRISTINA PRAMUDJI, M.D.:			6	BY MR. FAES:		
7	BY MR. FAES	145		7	Q. Dr. Pramudji, we're back on the		
8	BY MR. GAGE	255		8	record after an overnight break. Are you		
9	BY MR. FAES	264		9	ready to proceed?		
10				10	A. Yes.		
11	CERTIFICATE	267		11	Q. Doctor, before we broke last		
12	ERRATA	276		12	night, we were discussing some things about		
13	ACKNOWLEDGMENT OF DEPONENT		270	13	the Prosima and Prolift IFU, but before we		
14	LAWYER'S NOTES	271		14	get back into that, I just want to ask you a		
15				15	different question before I forget.		
16				16	Do you do hernia repairs in		
17				17	your practice?		
18				18	A. Abdominal wall hernia repairs?		
19				19	Q. Yes.		
20				20	A. No.		
21				21	Q. Have you ever done hernia		
22				22	repairs in your medical career?		
23				23	A. Yes, I have done them in my		
24				24	training, and maybe a small umbilical hernia		
Page 144				Page 146			
1	DEPOSITION EXHIBITS			1	repair on a case years ago.		
2	CHRISTINA PRAMUDJI, M.D.			2	Q. When was that?		
3	March 24, 2016			3	A. I don't know. Eight or		
4	NUMBER DESCRIPTION MARKED			4	ten years ago. We were going in for other		
5	Exhibit 11 Gynecare Prosima IFU	155		5	reasons and just put in a couple of sutures		
6	Exhibit 12 Gynecare Gynemesh PS IFU	162		6	at that time.		
7	Exhibit 13 Christina Pramudji	181		7	Q. Do you sometimes find, when		
8	Reliance List, in			8	you're repairing a prolapse, small umbilical		
9	Addition to Materials			9	hernias that need repair?		
10	Referenced in Report,			10	A. Occasionally find an umbilical		
11	MDL Wave I			11	hernia or an inguinal hernia. My norm is to		
12	Exhibit 14 03/29/2009 through	243		12	call general surgery and have them come in		
13	03/30/2009 E-mail String			13	and repair it.		
14	Exhibit 15 02/27/2008 Letter,	246		14	Q. Okay. Thank you. You		
15	Ethicon Women's Health &			15	anticipated my next question, which is, it's		
16	Urology to Price St.			16	your typical practice not to try to repair		
17	Hilaire			17	those small umbilical hernias yourself but to		
18	Exhibit 16 01/13/2009 E-mail,	247		18	refer it out to a physician who has more		
19	Chaves to Lynn, et al,			19	experience in that area?		
20	with Attachment			20	A. That's correct.		
21	Exhibit 17 Zoomerang Questions	247		21	Q. When you -- do you recall		
22	Comments - Dave Robinson			22	the -- you might have already answered this.		
23				23	Do you recall approximately when these		
24				24	hernias were that you repaired, the couple		

Christina Pramudji, M.D.

<p style="text-align: right;">Page 147</p> <p>1 that you did years ago?</p> <p>2 A. I don't recall.</p> <p>3 Q. Do you recall what -- if you</p> <p>4 used polypropylene mesh to repair those</p> <p>5 hernias?</p> <p>6 A. On those incidental cases, that</p> <p>7 would have just been sutures. But in</p> <p>8 residency when I repaired multiple during my</p> <p>9 general surgery, and that would have been</p> <p>10 going back to 1996, 1997, then we would use</p> <p>11 mesh.</p> <p>12 Q. Do you recall what meshes you</p> <p>13 used in 1996 --</p> <p>14 A. No.</p> <p>15 Q. -- at that time? But it's fair</p> <p>16 to say it wouldn't have been the Gynemesh PS</p> <p>17 in 1996 because it wasn't being made at that</p> <p>18 time, correct?</p> <p>19 A. That's correct.</p> <p>20 Q. So getting back to the IFU, let</p> <p>21 me ask you this, Doctor. If Ethicon said</p> <p>22 something in the IFU which Ethicon knew not</p> <p>23 to be true, would you agree that that would</p> <p>24 be wrongful?</p>	<p style="text-align: right;">Page 149</p> <p>1 Q. So what -- in what situations</p> <p>2 do you believe it would not be wrongful for</p> <p>3 Ethicon to make claims about that it had no</p> <p>4 data to support?</p> <p>5 A. I don't know. That's a very</p> <p>6 difficult question to answer. It's a</p> <p>7 hypothetical within a hypothetical, so I</p> <p>8 don't know if I could come up with any</p> <p>9 specific things.</p> <p>10 Q. So as you sit here today, your</p> <p>11 answer to the question if Ethicon made claims</p> <p>12 about the mesh in the Prolift or Prosima</p> <p>13 device that Ethicon had no data to support,</p> <p>14 your answer to whether or not that would be</p> <p>15 wrongful would be "it depends," but you can't</p> <p>16 think of any situations, as you sit here</p> <p>17 today, in which it would be okay?</p> <p>18 MR. GAGE: Object to form.</p> <p>19 A. That's correct.</p> <p>20 BY MR. FAES:</p> <p>21 Q. Are you aware of anything in</p> <p>22 the Prolift or Prosima IFU as to which anyone</p> <p>23 at Ethicon has admitted that there was not</p> <p>24 data to support the claim about the mesh?</p>
<p style="text-align: right;">Page 148</p> <p>1 A. Yes. I mean, depending on --</p> <p>2 yeah, I think if there's something that they</p> <p>3 knew not to be wrongful and it had -- it was</p> <p>4 a substantial fact, I would have to say that</p> <p>5 would be wrong.</p> <p>6 Q. If Ethicon made claims about</p> <p>7 the mesh in the Prolift or Prosima device</p> <p>8 that Ethicon had no data to support, would</p> <p>9 that be wrongful?</p> <p>10 A. It depends on what their --</p> <p>11 what issues they're referring to.</p> <p>12 Q. So your answer to that question</p> <p>13 is "it depends"?</p> <p>14 A. That's correct, it depends.</p> <p>15 Q. If Ethicon made claims about</p> <p>16 the mesh in the Prolift or Prosima device</p> <p>17 which it had no data to support and those</p> <p>18 claims were related to the clinical effects</p> <p>19 of the mesh, would that be wrongful?</p> <p>20 A. It still depends on what it is.</p> <p>21 It's -- you start out with a certain body of</p> <p>22 data and then the -- you gather more data as</p> <p>23 you go along. So it depends on what the</p> <p>24 issue is.</p>	<p style="text-align: right;">Page 150</p> <p>1 A. Not that I'm aware of.</p> <p>2 Q. If that occurred and the</p> <p>3 statement in the IFU affected the clinical</p> <p>4 performance of the mesh, would you agree that</p> <p>5 that would be a failure to provide adequate</p> <p>6 and appropriate warnings about the Prolift</p> <p>7 and Prosima devices?</p> <p>8 A. Can you repeat the question?</p> <p>9 MR. FAES: May I have the court</p> <p>10 reporter read it back because I don't</p> <p>11 know if I can.</p> <p>12 (Question Read Back.)</p> <p>13 MR. GAGE: Object to form.</p> <p>14 A. What is "that"? What was</p> <p>15 "that" referring to at the beginning? What</p> <p>16 was the question before that?</p> <p>17 BY MR. FAES:</p> <p>18 Q. The previous question was about</p> <p>19 making a claim which there was no data to</p> <p>20 support, a claim about the mesh which</p> <p>21 affected its clinical performance.</p> <p>22 A. Okay. Now, can you read the</p> <p>23 last question one more time, please.</p> <p>24 (Question Read Back.)</p>

4 (Pages 147 to 150)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 151</p> <p>1 MR. GAGE: Object to form. 2 A. No, not necessarily. Again, it 3 depends. 4 BY MR. FAES: 5 Q. In what situations would that 6 not be a failure to provide an adequate and 7 appropriate warning? 8 A. I can't think of any specific 9 examples that I can give you. 10 Q. Are you aware of any Ethicon 11 deposition testimony admitting anything about 12 the mesh which is contrary to what is 13 represented in the IFU regarding the 14 Gynemesh PS or the devices which contain the 15 Gynemesh PS? 16 A. Not that I can recall sitting 17 here right now. 18 Q. If that occurred, would you 19 agree that it would be a failure to provide 20 adequate and appropriate warnings about the 21 Prosima, Prolift and Gynemesh PS? 22 MR. GAGE: Objection. 23 A. No, not necessarily. 24 BY MR. FAES:</p>	<p style="text-align: right;">Page 153</p> <p>1 the Prosima? 2 A. It depends on the patient. So 3 there's some patients that really need to 4 have a mesh augmentation and some patients 5 that can do okay without a mesh augmentation. 6 Q. Is your answer the same with 7 regard to the Prolift device? 8 A. Yes. 9 Q. Is your answer the same with 10 regard to the Gynemesh PS device? 11 A. Yes. Some patients really 12 benefit from mesh augmentation, many 13 patients. 14 MR. FAES: I'm going to move to 15 strike after the answer "yes." 16 BY MR. FAES: 17 Q. So is it your opinion that even 18 if a patient can benefit from mesh 19 augmentation, that using -- that -- strike 20 that. 21 So is it your opinion that even 22 if a patient can benefit from mesh 23 augmentation, it's your opinion that in those 24 patients mesh should not be used judiciously?</p>
<p style="text-align: right;">Page 152</p> <p>1 Q. So it's your opinion that it's 2 not a failure to warn, even if Ethicon 3 provided information about the mesh it knew 4 to be unsupported or made an affirmative 5 representation about the mesh it knew not to 6 be true, even if it affected its clinical 7 performance? That's okay with you? 8 MR. GAGE: Object to form. 9 A. That's a very long question. 10 That's correct, not necessarily. There are 11 certain -- I can imagine certain situations 12 where there would be -- where that would not 13 be a problem at all. 14 BY MR. FAES: 15 Q. Okay. Let me ask you the -- 16 strike that. 17 Let me ask if you -- you if 18 the -- strike that again. 19 Let me ask you if the following 20 statement is true with regard to the Prosima. 21 Considering that native tissue repair is an 22 option for many women, it makes sense to use 23 vaginal mesh judiciously in vaginal mesh 24 repairs. Is that a true statement regarding</p>	<p style="text-align: right;">Page 154</p> <p>1 MR. GAGE: Object to form. 2 A. No. My opinion is that all 3 surgeries should be done judiciously, whether 4 with mesh or with biological graft or without 5 mesh. Every surgery is done judiciously. 6 BY MR. FAES: 7 Q. So it's your opinion that while 8 every surgery should be done judiciously, it 9 doesn't make sense to use vaginal mesh 10 judiciously for some mesh repairs if the 11 patient can benefit from the mesh? 12 MR. GAGE: Object to form. 13 A. No, I think every surgery is 14 done judiciously, whether using mesh or not. 15 BY MR. FAES: 16 Q. So I'm just trying to 17 understand your opinions, Doctor. You 18 think -- you believe every surgery should be 19 done judiciously. Do you believe vaginal 20 mesh should be used judiciously in every 21 case? 22 A. Absolutely. 23 Q. Okay. Let me ask you something 24 very specific about the Prosima IFU. What</p>

5 (Pages 151 to 154)

Christina Pramudji, M.D.

Page 155	Page 157
<p>1 specific information would you say actually 2 needed to be in there to warn doctors about 3 complications? What do you think it needs to 4 say? 5 A. Well, the only risk unique to a 6 mesh implant is a mesh exposure or erosion. 7 And other than that, I think they could say 8 it has the same risks as any other pelvic 9 surgery. 10 Q. So your opinion is, if the 11 adverse reaction section of the Prosima IFU 12 said the Prosima has the same risks as any 13 pelvic surgery and also the risk of erosion 14 or exposure of the mesh, that would be -- 15 that would be a sufficient IFU with regard to 16 the adverse reaction section? 17 A. Yes. 18 Q. But you know -- and feel free 19 to refer to the Prosima IFU in front of you 20 that we marked yesterday. I can't remember. 21 We'll re-mark it as Exhibit 11 since the 22 court reporter ran off with the exhibits 23 yesterday. 24 (Deposition Exhibit 11 marked.)</p>	<p>1 question again, and I'm going to ask you 2 to -- if you need to offer an explanation 3 after the answer, do so, but if you can, 4 please first answer the question yes or no. 5 MR. GAGE: Hang on a second. 6 As I understand it, the court rules 7 are she can answer yes, followed by an 8 explanation; no, followed by an 9 explanation; or she can answer, I 10 can't answer it yes or no. 11 MR. FAES: I'll agree with 12 that. 13 MR. GAGE: Those are the rules 14 of court. 15 BY MR. FAES: 16 Q. So is it your opinion as an 17 expert for Ethicon that everything in this 18 adverse reaction section for the Prosima IFU, 19 other than erosion exposure and the same 20 risks as any pelvic surgery, are unnecessary? 21 A. I wouldn't say yes or no to 22 that. I would say that's fine if they put 23 that in there, but it doesn't really add 24 anything to the knowledge of a pelvic</p>
Page 156	Page 158
<p>1 BY MR. FAES: 2 Q. So is it your opinion that 3 everything else that's in this adverse 4 reaction section is unnecessary? 5 A. Yes. 6 Q. So it's your opinion, as an 7 expert for Ethicon, that Ethicon puts 8 unnecessary information in the IFU? 9 A. That's a funny way to put it. 10 I would say it's redundant for a pelvic 11 surgeon that would be using this. They would 12 know about all these risks. And someone 13 that's using the Prosima, frankly, would know 14 about the risk of mesh exposure. So I do -- 15 I think -- I wouldn't say they're 16 unnecessary. I would just say that they're 17 redundant and just sort of extra information. 18 I don't have a problem with it. They can 19 put -- 20 Q. I'm going to re-ask the 21 question. I think you answered the question 22 in there somewhere, but you added a lot of 23 other things about whether you thought it was 24 redundant or not. So I'm going to ask the</p>	<p>1 surgeon. 2 Q. But you can't answer whether or 3 not the -- any of the extra information is 4 unnecessary or not? 5 A. That's correct. 6 Q. Would you agree that providing 7 this information that -- other than -- strike 8 that. 9 Would you provide [sic] that 10 providing information in the adverse reaction 11 section, other than just erosion exposure and 12 the same risks as pelvic surgery, can be 13 helpful to some surgeons in reminding them 14 about the adverse reactions of the device? 15 MR. GAGE: Object to form. 16 A. Sure, it can be a reminder. 17 Sort of like McDonald's coffee, be careful, 18 it's hot, don't spill it. 19 MR. FAES: I'm going to move -- 20 object and move to strike after the 21 word "reminder." 22 BY MR. FAES: 23 Q. Doctor, I'm going to ask you 24 about some -- a list of adverse reactions,</p>

6 (Pages 155 to 158)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 159</p> <p>1 and I'm going to ask you if they are 2 potential risks of the Gynemesh PS, Prolift 3 and Prosima device. Okay? 4 Is bleeding a risk of those 5 devices? 6 A. Yes, it is, as with all pelvic 7 surgery. 8 Q. Is hemorrhage or hematoma a 9 risk of those devices? 10 A. Yes, as it is with all pelvic 11 surgery. 12 Q. Is urinary incontinence a risk 13 of those devices? 14 A. Yes, as with all pelvic 15 surgery. 16 Q. Is urge incontinence a risk of 17 those devices? 18 A. Yes, same with all pelvic 19 surgery. 20 Q. Is urinary frequency, urinary 21 retention or obstruction a risk of those 22 devices? 23 A. Yes, same with other pelvic 24 surgeries.</p>	<p style="text-align: right;">Page 161</p> <p>1 Q. Pelvic pain or pain with 2 intercourse which in some patients may not 3 resolve? 4 A. Yes, same as other pelvic 5 surgeries. 6 Q. Excessive contraction or 7 shrinkage of the tissue surrounding the mesh? 8 A. Yes. And that -- you can have 9 excessive contraction even without mesh. 10 Q. Punctures or lacerations of 11 vessels, nerve structures or organs, 12 including the bladder, urethra or bowel which 13 may occur and may require surgical repair? 14 A. Yes, same as other pelvic 15 surgeries. 16 Q. Neuromuscular problems, 17 including acute and/or chronic pain in the 18 groin, thigh, leg, pelvic and/or abdominal 19 area which may occur? 20 A. Yes, same as other pelvic 21 surgeries. 22 Q. And all of these adverse 23 reactions may require surgical treatment? 24 A. Yes, the same as other pelvic</p>
<p style="text-align: right;">Page 160</p> <p>1 Q. Is voiding obstruction a risk 2 of those devices? 3 A. Yes, same with other pelvic 4 surgeries. 5 Q. Acute and/or chronic pain? 6 A. Yes, same with other pelvic 7 surgeries. 8 Q. Wound dehiscence? 9 A. Yes, same as other pelvic 10 surgeries. 11 Q. Nerve damage? 12 A. Yes, same as other pelvic 13 surgeries. 14 Q. Recurrent prolapse? 15 A. Yes, same as other pelvic 16 surgeries. 17 Q. Foreign body response? 18 A. Yes, same with other pelvic 19 surgeries. 20 Q. The potential to impair normal 21 voiding function for a variable length of 22 time? 23 A. Yes, same as other pelvic 24 surgeries.</p>	<p style="text-align: right;">Page 162</p> <p>1 surgeries. 2 Q. Is it your opinion that all of 3 those risks that I just read to you are 4 unnecessary to be included in the Prolift, 5 Prosima or Gynemesh IFU? 6 A. That's correct. They are part 7 of the body of knowledge of pelvic surgeons, 8 so I think they don't necessarily have to be 9 in there. 10 Q. Do you know whether or not 11 those risks are in the Gynemesh PS IFU today? 12 A. I would have to review it. I 13 don't have a problem if they're in there. 14 Q. Do you know whether or not all 15 of the adverse events I just read to you were 16 added in 2015? 17 A. I would have to look at it. I 18 don't know. 19 (Deposition Exhibit 12 marked.) 20 BY MR. FAES: 21 Q. I'm going to hand you what's 22 been marked as Exhibit No. 12 to your 23 deposition. 24 MR. FAES: Do you want one,</p>

7 (Pages 159 to 162)

Christina Pramudji, M.D.

Page 163	Page 165
<p>1 William?</p> <p>2 MR. GAGE: Yeah. Thank you.</p> <p>3 BY MR. FAES:</p> <p>4 Q. So I'll represent to you that</p> <p>5 those are all risks that were added to the</p> <p>6 Gynemesh PS IFU beginning with this revision</p> <p>7 that Ethicon released in 2015, and the front</p> <p>8 page of this is dated February 3rd, 2015.</p> <p>9 Do you know whether or not</p> <p>10 these are all risks of the Prosima, Prolift</p> <p>11 and Gynemesh PS device that Ethicon knew</p> <p>12 about when those devices were first launched</p> <p>13 onto the market?</p> <p>14 MR. GAGE: Object to form.</p> <p>15 A. I'm not sure. I don't know.</p> <p>16 BY MR. FAES:</p> <p>17 Q. Do you know whether or not</p> <p>18 Ethicon could've chosen to include all of</p> <p>19 these risks in their IFU --</p> <p>20 A. I would --</p> <p>21 Q. -- from the -- sorry, I wasn't</p> <p>22 done with the question. I'll start over.</p> <p>23 Do you know whether or not</p> <p>24 Ethicon could have chosen to include all of</p>	<p>1 Ethicon would knowingly put things in the IFU</p> <p>2 that it believed to be unnecessary?</p> <p>3 MR. GAGE: Object to form.</p> <p>4 A. I don't know what they knew or</p> <p>5 didn't know.</p> <p>6 BY MR. FAES:</p> <p>7 Q. Now, you -- strike that.</p> <p>8 You testified that it was your</p> <p>9 typical practice to read the IFU before</p> <p>10 implanting the device for the first time,</p> <p>11 right?</p> <p>12 A. Correct.</p> <p>13 Q. And you typically wouldn't</p> <p>14 re-review the IFU unless you were aware that</p> <p>15 there was a change to that IFU, correct?</p> <p>16 A. That's correct.</p> <p>17 Q. Would you have any way of</p> <p>18 knowing, unless you closely examined the IFU,</p> <p>19 that there had been an important IFU update?</p> <p>20 A. Not that I'm aware of.</p> <p>21 Q. Do you think it would be --</p> <p>22 strike that.</p> <p>23 You're a past user of</p> <p>24 Gynemesh PS, correct?</p>
Page 164	Page 166
<p>1 these risks in their IFUs for the Gynemesh</p> <p>2 PS, Prolift and Prosima device beginning from</p> <p>3 the first day that they were launched in the</p> <p>4 United States?</p> <p>5 A. I would have to say, sure,</p> <p>6 theoretically, you could come up with a long</p> <p>7 laundry list of things that you could put in</p> <p>8 the IFU. So, sure, theoretically they could</p> <p>9 have put them in from the beginning.</p> <p>10 Q. Do you know whether or not</p> <p>11 Ethicon felt it was necessary to add these</p> <p>12 adverse events to their IFU in 2015?</p> <p>13 A. No, I don't know what they</p> <p>14 thought.</p> <p>15 Q. Do you believe, as an expert</p> <p>16 for Ethicon, that Ethicon would knowingly put</p> <p>17 things in the IFU that it believed to be</p> <p>18 unnecessary?</p> <p>19 MR. GAGE: Object to form.</p> <p>20 A. Can you read back the question</p> <p>21 or can you repeat it?</p> <p>22 BY MR. FAES:</p> <p>23 Q. I'll repeat it. Do you</p> <p>24 believe, as an expert for Ethicon, that</p>	<p>1 A. Correct.</p> <p>2 Q. Do Ethicon sales reps know that</p> <p>3 you've used Gynemesh PS and products that</p> <p>4 contain Gynemesh PS in the past?</p> <p>5 A. Yes.</p> <p>6 Q. Has anyone from Ethicon ever</p> <p>7 informed you that the IFU for the Gynemesh PS</p> <p>8 was updated in 2015?</p> <p>9 A. No, and I wouldn't expect them</p> <p>10 to. If you have a surgeon that's familiar</p> <p>11 with the product, they're having good</p> <p>12 results, it's not going to change anything.</p> <p>13 Q. Isn't it possible that there</p> <p>14 are -- strike that.</p> <p>15 Do you think it would be a</p> <p>16 reasonable thing to do, for Ethicon to inform</p> <p>17 doctors that there is a new IFU for its</p> <p>18 products out there that may contain important</p> <p>19 adverse reactions that were not contained in</p> <p>20 the previous IFU?</p> <p>21 A. Sure, it's reasonable. I</p> <p>22 wouldn't say that's unreasonable.</p> <p>23 Q. Do you think it would be</p> <p>24 helpful for Ethicon to inform doctors that</p>

8 (Pages 163 to 166)

Christina Pramudji, M.D.

Page 167	Page 169
<p>1 there's a new IFU out there for its products</p> <p>2 that may contain important adverse reactions</p> <p>3 that were not contained in the previous IFU?</p> <p>4 A. Not particularly, because we</p> <p>5 already know about all this.</p> <p>6 Q. So you believe that every</p> <p>7 surgeon in America knows about all of the new</p> <p>8 adverse reactions that were added to the</p> <p>9 Gynemesh PS IFU in 2015?</p> <p>10 A. Did you mean to say "every</p> <p>11 surgeon" or "every pelvic surgeon"?</p> <p>12 Q. I'll restate it as every pelvic</p> <p>13 surgeon. So you believe that every pelvic</p> <p>14 surgeon in America knows about all of the new</p> <p>15 adverse reactions that were added to the</p> <p>16 Gynemesh PS IFU in 2015?</p> <p>17 A. Well, I don't know what they</p> <p>18 would know about the IFU. But I would say</p> <p>19 that a pelvic surgeon that is familiar with</p> <p>20 pelvic surgery, familiar with mesh, would</p> <p>21 definitely be aware of these adverse</p> <p>22 reactions.</p> <p>23 MR. FAES: I'm going to object</p> <p>24 and move to strike after the word</p>	<p>1 use for a particular medical device that the</p> <p>2 FDA deemed important, do you think that that</p> <p>3 would be something that would be reasonable</p> <p>4 for a medical device company to communicate</p> <p>5 to surgeons who they knew used the device?</p> <p>6 A. Again, it depends what it is,</p> <p>7 depends if it's going to affect how you</p> <p>8 implant it, you use it and what the nature of</p> <p>9 the update is.</p> <p>10 Q. I think yesterday you testified</p> <p>11 that you believe the Gynemesh PS was still</p> <p>12 indicated for transvaginal placement.</p> <p>13 A. I believe it is.</p> <p>14 Q. Do you want to take a moment to</p> <p>15 read the indications for use in this updated</p> <p>16 2015 IFU and tell me if you -- after</p> <p>17 reviewing that, if you still believe that's</p> <p>18 the case?</p> <p>19 (Witness Reviews Document.)</p> <p>20 A. It says here that it's</p> <p>21 "indicated as a bridging material for apical</p> <p>22 vaginal and uterine prolapse where surgical</p> <p>23 treatment (laparotomy or laparoscopic</p> <p>24 approach) is warranted."</p>
Page 168	Page 170
<p>1 "IFU."</p> <p>2 BY MR. FAES:</p> <p>3 Q. Have you done any kind of</p> <p>4 research or survey to determine -- strike</p> <p>5 that.</p> <p>6 Have you done any kind of</p> <p>7 research or survey or study to determine what</p> <p>8 the typical pelvic surgeon in the United</p> <p>9 States knows about the adverse reactions of</p> <p>10 the Gynemesh PS, Prolift and Prosima device?</p> <p>11 A. No, I haven't done any research</p> <p>12 like that.</p> <p>13 Q. If there were an important</p> <p>14 update to the indications for use for a</p> <p>15 particular medical device, do you think that</p> <p>16 would be something that would be reasonable</p> <p>17 for a medical device company to communicate</p> <p>18 to surgeons who they knew used the device?</p> <p>19 A. Depends on what you mean by</p> <p>20 "important." Who considers it important?</p> <p>21 The surgeons or the attorneys?</p> <p>22 Q. Well, you know that the -- I'm</p> <p>23 not -- okay. Let me ask it this way. If</p> <p>24 there were a update to the indications for</p>	<p>1 So apparently they're using it</p> <p>2 more for intraabdominal for that indication</p> <p>3 at this point. So I was not aware of that</p> <p>4 change.</p> <p>5 BY MR. FAES:</p> <p>6 Q. Were you aware that this change</p> <p>7 actually occurred not with the 2015 IFU but</p> <p>8 with the 2013 IFU?</p> <p>9 A. No, I didn't know about that.</p> <p>10 Q. So you didn't know, as an</p> <p>11 expert offering opinions on the Gynemesh PS</p> <p>12 mesh, that the indications for use for the</p> <p>13 device changed nearly three years ago?</p> <p>14 A. No.</p> <p>15 MR. GAGE: Objection.</p> <p>16 A. As I mentioned, I haven't used</p> <p>17 Gynemesh for several years, so I was not</p> <p>18 aware of that.</p> <p>19 BY MR. FAES:</p> <p>20 Q. Since the indications for use</p> <p>21 for the Gynemesh PS mesh have changed as of</p> <p>22 2013, would it be reasonable to assume that</p> <p>23 indications for use for the Prosima and</p> <p>24 Prolift device would have changed as well if</p>

9 (Pages 167 to 170)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 171</p> <p>1 those products were still on the market?</p> <p>2 MR. GAGE: Object to form.</p> <p>3 A. I don't think so because those</p> <p>4 are specifically transvaginal kits. So I</p> <p>5 don't know what other indication that they</p> <p>6 could put besides transvaginal placement.</p> <p>7 BY MR. FAES:</p> <p>8 Q. But you know that the FDA has</p> <p>9 told Ethicon that they can no longer sell the</p> <p>10 Prosima or Prolift device unless they</p> <p>11 complete a 522 order, correct?</p> <p>12 A. I believe that's correct.</p> <p>13 MR. GAGE: Object to form.</p> <p>14 BY MR. FAES:</p> <p>15 Q. And you know that the FDA</p> <p>16 agreed that the Prolift and Prosima 522 plans</p> <p>17 could be placed on hold if Ethicon -- if</p> <p>18 Ethicon agreed not to sell those devices</p> <p>19 anymore, correct?</p> <p>20 A. I don't know about those</p> <p>21 details.</p> <p>22 Q. You don't know about those</p> <p>23 details?</p> <p>24 A. No.</p>	<p style="text-align: right;">Page 173</p> <p>1 BY MR. FAES:</p> <p>2 Q. Do you know that -- whether or</p> <p>3 not Ethicon negotiated with the FDA to keep</p> <p>4 Gynemesh PS on the market, and a condition of</p> <p>5 their being allowed to keep it on the market</p> <p>6 was to remove the transvaginal indication for</p> <p>7 the Gynemesh PS and have it be indicated for</p> <p>8 abdominal placement only?</p> <p>9 MR. GAGE: Object to form.</p> <p>10 A. I don't know about that.</p> <p>11 BY MR. FAES:</p> <p>12 Q. Do you think that would be an</p> <p>13 important fact to consider in forming your</p> <p>14 opinions in this case?</p> <p>15 A. No, I don't think that would</p> <p>16 affect my opinion.</p> <p>17 Q. Do you think a surgeon who has</p> <p>18 been using the Gynemesh PS transvaginally</p> <p>19 prior to the IFU update in 2013 would want to</p> <p>20 know about the indication-for-use change if</p> <p>21 he were going to continue using it after the</p> <p>22 indication-for-use change in 2013?</p> <p>23 MR. GAGE: Object to form.</p> <p>24 A. I think if a surgeon is using</p>
<p style="text-align: right;">Page 172</p> <p>1 Q. Are you aware that if Ethicon</p> <p>2 decides to start selling those devices again,</p> <p>3 they need to notify the FDA before doing so?</p> <p>4 A. I don't know about that detail</p> <p>5 either.</p> <p>6 Q. Assuming that that's true, do</p> <p>7 you think it's reasonable, since it's been</p> <p>8 three years -- over three years since the</p> <p>9 Prosima and Prolift devices were sold and the</p> <p>10 FDA has changed -- had -- strike that.</p> <p>11 Assuming that's true, do you</p> <p>12 think it's reasonable to assume that since</p> <p>13 it's been three years since the Prosima and</p> <p>14 Prolift device has been sold and the</p> <p>15 indications for use for the mesh that is used</p> <p>16 in those devices has changed in that time,</p> <p>17 that the FDA would look closely at the IFUs</p> <p>18 for those devices before allowing that to be</p> <p>19 put -- placed back on the market?</p> <p>20 MR. GAGE: Object to form.</p> <p>21 A. I would imagine that they</p> <p>22 would, but I don't know what the FDA process</p> <p>23 is in detail.</p> <p>24</p>	<p style="text-align: right;">Page 174</p> <p>1 it and is comfortable with it, having good</p> <p>2 results with it, even transvaginally, it's</p> <p>3 not important for them to know.</p> <p>4 BY MR. FAES:</p> <p>5 Q. So it's your testimony that</p> <p>6 you, as a physician, wouldn't want to know if</p> <p>7 you were using a medical device off label</p> <p>8 before you used it off label?</p> <p>9 A. If you're using something with</p> <p>10 good results, literature supports safety and</p> <p>11 efficacy, I think the change of -- the</p> <p>12 off-label change of indication is simply,</p> <p>13 really, semantics in that situation and,</p> <p>14 yeah, it -- I guess you could say it would be</p> <p>15 helpful to know. But I think you would still</p> <p>16 be able to support your use of the device off</p> <p>17 label based on your own results and based on</p> <p>18 the literature that's out there.</p> <p>19 MR. FAES: I'm going to object</p> <p>20 and move to strike just because I'm</p> <p>21 not sure what your answer there was.</p> <p>22 Maybe it's my fault. Maybe I asked a</p> <p>23 bad question, so I'll ask it a little</p> <p>24 bit differently.</p>

10 (Pages 171 to 174)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 175</p> <p>1 BY MR. FAES:</p> <p>2 Q. Would you, as a physician, want</p> <p>3 to know if you were using a medical device</p> <p>4 off label before you used the device?</p> <p>5 A. Not necessarily.</p> <p>6 Q. Do you think other physicians</p> <p>7 would want to know if they were using the</p> <p>8 device off label before they used that</p> <p>9 device?</p> <p>10 A. Not necessarily. I can</p> <p>11 certainly conceive of how this -- how you</p> <p>12 could continue using this off label and feel</p> <p>13 very comfortable and be able to support your</p> <p>14 position for using it off label, even if you</p> <p>15 found out after the fact.</p> <p>16 Q. So is it your opinion -- strike</p> <p>17 that.</p> <p>18 So is it not your typical</p> <p>19 practice to read the instruction -- strike</p> <p>20 that.</p> <p>21 Is it not your typical practice</p> <p>22 to read the indications for use for a medical</p> <p>23 device before deciding how to use that</p> <p>24 medical device?</p>	<p style="text-align: right;">Page 177</p> <p>1 the indications for use for a medical device</p> <p>2 before deciding how to use that medical</p> <p>3 device?</p> <p>4 A. I don't know the answer to that</p> <p>5 question. I don't know how many surgeons</p> <p>6 look at the IFU. I don't know. Because a</p> <p>7 lot of training you learn from other</p> <p>8 surgeons. We rarely learn from the IFU.</p> <p>9 MR. FAES: I'm going to object</p> <p>10 and move -- move to strike after the</p> <p>11 third "I don't know."</p> <p>12 BY MR. FAES:</p> <p>13 Q. Is it your testimony that the</p> <p>14 indications for use in the IFU don't guide</p> <p>15 your decision on how to use that device?</p> <p>16 A. To a certain degree it may</p> <p>17 guide how I use the device, but it's really</p> <p>18 not the primary thing that I rely on, if that</p> <p>19 makes sense. It's sort of supplemental.</p> <p>20 Okay, let's see what it says here, see if</p> <p>21 there's any nuance that I'm not aware of, and</p> <p>22 then proceed as such.</p> <p>23 Q. Would you agree with me that if</p> <p>24 a physician were to place the Gynemesh PS</p>
<p style="text-align: right;">Page 176</p> <p>1 A. Like I said before, when you</p> <p>2 first use something, you review the IFU. But</p> <p>3 after you use it and you're comfortable with</p> <p>4 it, you apply your skills as a surgeon.</p> <p>5 That's what's more important, not -- we don't</p> <p>6 live and die by the IFU. We don't function</p> <p>7 based on the IFU. We function based on our</p> <p>8 skills and training.</p> <p>9 MR. FAES: I'm going to object</p> <p>10 and move to strike. Again, I may have</p> <p>11 asked a bad question so I'll try to</p> <p>12 ask it a little bit better.</p> <p>13 BY MR. FAES:</p> <p>14 Q. Is it your typical practice to</p> <p>15 read the indications for use for a medical</p> <p>16 device before deciding how to use that</p> <p>17 medical device?</p> <p>18 A. No. I don't use it to decide</p> <p>19 how to use the medical device. I use it to</p> <p>20 make sure I understand what the device</p> <p>21 offers, make sure I understand how it's</p> <p>22 intended for use.</p> <p>23 Q. Do you think it's typical</p> <p>24 practice for other pelvic surgeons to read</p>	<p style="text-align: right;">Page 178</p> <p>1 transvaginally today in a surgery in the</p> <p>2 United States, that use would be off label?</p> <p>3 A. Yes, that's correct.</p> <p>4 Q. Would you agree with me that if</p> <p>5 a physician were to place the Gynemesh PS</p> <p>6 transvaginally today in the surgery -- strike</p> <p>7 that.</p> <p>8 Would you agree with me that if</p> <p>9 a physician were to place the Gynemesh PS</p> <p>10 transvaginally today in the United States,</p> <p>11 that would be contrary to the indications for</p> <p>12 use as currently stated in the IFU?</p> <p>13 A. Yes, I would have to agree with</p> <p>14 that based on what the IFU says here.</p> <p>15 Q. I think I'm done with that for</p> <p>16 now. You can set that aside.</p> <p>17 Doctor, I'm going to mark</p> <p>18 another copy of your --</p> <p>19 MR. GAGE: FYI, the Wolfe depo</p> <p>20 has been postponed. I just got the</p> <p>21 e-mail.</p> <p>22 MR. FAES: Exciting news. Do</p> <p>23 you have another copy of her op</p> <p>24 report, William?</p>

11 (Pages 175 to 178)

Christina Pramudji, M.D.

Page 179	Page 181
<p>1 (Discussion Off The Record.) 2 BY MR. FAES: 3 Q. Doctor, I'm just going to ask 4 you -- I'm going to want to ask you a few 5 questions about your pelvic organ prolapse 6 report. If you need to refer to -- back to 7 it, the court reporter took off with it. I 8 can give you my copy if you really need it. 9 MR. GAGE: Well, but you had it 10 in your notebook, didn't you? 11 THE WITNESS: That big one. I 12 think it might be that one on the top. 13 BY MR. FAES: 14 Q. I think you can probably answer 15 these questions without looking at it, but I 16 don't want you to be handicapped by not 17 having it available. 18 MR. FAES: Yeah, we're still on 19 the Prolift deposition. 20 BY MR. FAES: 21 Q. Now, in your report in your 22 reliance list, there's medical literature 23 that you cite in both your report and on your 24 reliance list. Have you read all those</p>	<p>1 your opinions in this case? 2 A. It depends on what it is. 3 Q. But you would agree that it's 4 possible that there could be literature or 5 data out there that could change your 6 opinions in this case and you can't know 7 whether it's significant unless you see it, 8 correct? 9 MR. GAGE: Object to form. 10 A. No, I would disagree. I think 11 that's very unlikely because I feel very 12 comfortable with the literature that I have 13 here and my own experience. My opinions are 14 very firm. 15 BY MR. FAES: 16 Q. So you believe it's very 17 unlikely. But do you believe it's possible? 18 A. I think it's next to 19 impossible. 20 Q. I'm just going to leave that 21 alone. 22 (Deposition Exhibit 13 marked.) 23 BY MR. FAES: 24 Q. Just so you have it, Doctor,</p>
Page 180	Page 182
<p>1 articles? 2 A. I've at least perused them. I 3 wouldn't say that I've read them all in 4 detail. 5 Q. Would you agree that the list 6 of medical literature and articles in your 7 report and your reliance list is not a 8 comprehensive list of all the articles and 9 literature that's available on the Prosima, 10 Gynemesh PS or Prolift? 11 A. Probably not. 12 Q. Is it possible there's clinical 13 data that you didn't see, which, if you saw, 14 could change your opinions in this case? 15 MR. GAGE: Object to form. 16 A. It's possible there's 17 literature I haven't seen, but I think I've 18 got the -- most of the level 1 literature, so 19 I doubt there's something that would change 20 my opinions. 21 BY MR. FAES: 22 Q. Would you agree with me that 23 unless you see such data, you can't assess 24 whether it's significant to you in forming</p>	<p>1 I'm going to -- you're going to need this 2 eventually for your TVT deposition later 3 anyway, I'm going to re-mark a copy of your 4 reliance list for all your expert reports as 5 Exhibit 13 for the record. 6 A. Okay. 7 Q. Now, there's a lot of different 8 articles that you cite in your Gynemesh PS, 9 Prolift and Prosima report. Did you 10 deliberately not cite to articles that were 11 not favorable to those products? 12 MR. GAGE: Object to form. 13 A. No, I didn't deliberately. I 14 tried to pick out the articles which I 15 thought had the best data as far as the most 16 rigorous data, whether it was favorable or 17 not. 18 BY MR. FAES: 19 Q. I'm going to shift gears a 20 little bit, Doctor, and ask you some 21 questions about the mesh properties of the 22 Gynemesh PS, Prolift and Prosima device. 23 Do you know whether or not the 24 amount of mesh placed in a woman's pelvis for</p>

12 (Pages 179 to 182)

Christina Pramudji, M.D.

Page 183	Page 185
<p>1 the treatment of prolapse has an effect on 2 the intensity and duration of the foreign 3 body reaction and inflammatory response? 4 A. I would say that the more 5 sutures, the more mesh, the more foreign 6 body -- it is a foreign body that's placed, 7 you're going to have more of a foreign body 8 reaction. 9 Q. So you would agree that, in 10 general, the larger the amount and weight of 11 the material, the greater the foreign body 12 reaction and inflammatory response will be? 13 A. Yes. More than likely. 14 However, that doesn't necessarily -- that's a 15 normal reaction that you would expect. It's 16 part of the wound healing. 17 MR. FAES: I'm going to object 18 and move to strike after the word 19 "likely." 20 BY MR. FAES: 21 Q. Doctor, am I correct that you 22 don't hold yourself out to be an expert with 23 regard to the design of medical device -- 24 strike that.</p>	<p>1 very confident and familiar with evaluating 2 the design based on those parameters. 3 BY MR. FAES: 4 Q. Is that the extent of the 5 opinions that I would expect you to offer on 6 the Prosima -- on the design of the Prosima, 7 rather? 8 MR. GAGE: Object to form. 9 A. I may have some other opinions 10 as far as they go to the mesh in general or 11 pelvic floor kits or surgery in general. 12 BY MR. FAES: 13 Q. So you would have opinions on 14 the design of the mesh in general or the 15 design of pelvic floor kits and surgery in 16 general? 17 A. Yes. 18 Q. Would those opinions on the 19 design go beyond how those devices -- you 20 believe those devices worked in your hands? 21 A. Yes, they potentially could. 22 Q. Well, you understand, Doctor, 23 that this is my opportunity here today to 24 learn what your opinions in this case might</p>
Page 184	Page 186
<p>1 Doctor, am I correct that you 2 don't hold yourself out to be an expert with 3 regard to the design of medical device kits 4 for the treatment of prolapse? 5 A. I would say that I am somewhat 6 of an expert in that area as far as being a 7 user of the devices and also being involved 8 in some of the labs that are held during the 9 development of devices that I've been 10 involved in. So as far as being asked to 11 evaluate different devices as they're being 12 produced, as far as that goes, I do have some 13 expertise in that area. 14 Q. Well, let me see if I can ask 15 it a different way. Am I correct that I 16 would not expect you to offer design -- 17 strike that. 18 Am I correct that I would not 19 expect you to offer opinions on the design of 20 the Prosima? 21 MR. GAGE: Object to form. 22 A. My opinions would go to how I 23 feel the design is based on use in my hands 24 and based on the patient results. So I feel</p>	<p>1 be. What other opinions might you offer on 2 the design of the Prosima or mesh kits or 3 mesh in general? 4 A. Well, opinions about the design 5 of the mesh in general, the way that the mesh 6 is configured, the size of the pores, the 7 materials that the mesh is made of. Or with 8 the kits, how they're designed, how they -- 9 the development of the kits, the nuances of 10 the trocars and how it worked in patients. 11 Q. Have you ever worked on the 12 design team for a medical device? 13 A. No, only on a consulting basis. 14 Q. Am I correct in that you're not 15 a biomedical engineer? 16 A. I'm not a biomedical engineer. 17 I studied it, but I'm not a biomedical 18 engineer. 19 Q. Do you hold yourself out as an 20 expert in biomedical engineering? 21 A. To the degree that it applies 22 to my practice, yes. 23 Q. Do you know what a design 24 failure modes analysis is?</p>

13 (Pages 183 to 186)

Christina Pramudji, M.D.

Page 187	Page 189
<p>1 A. I don't -- I'm not familiar 2 with that term. 3 Q. Is it fair to say that you have 4 never reviewed any design failure mode 5 analysis with respect to the Prosima, 6 Gynemesh PS or Prolift? 7 A. I may have, because just 8 breaking down that terminology, I don't -- I 9 can't give you a quick definition. But just 10 breaking it down, it sounds like it's just 11 testing the failure of the design with 12 some -- probably some mechanical stretching 13 or that sort of thing, but that's my 14 conjecture. So I may have read about that. 15 Q. Do you know what a process 16 failure modes effects analysis is? 17 A. I'm not familiar with that 18 term. 19 Q. Do you recall if you reviewed 20 any process failure modes effects analysis 21 with the Prosima, Prolift or Gynemesh PS 22 devices? 23 A. I'm not sure. 24 Q. Do you know what an</p>	<p>1 feel very knowledgeable about the type of the 2 mesh, the use of the mesh, behavior of the 3 mesh. 4 BY MR. FAES: 5 Q. Do you have any expertise or 6 specialized knowledge regarding whether or 7 not a 1-millimeter pore size when the mesh is 8 used in the body has any advantages or 9 disadvantages for the patient? 10 A. Yes. I've definitely studied 11 the pore sizes and I've seen how the mesh 12 behaves in the patients, and I feel like I 13 have a very in-depth knowledge about that. 14 Q. Let me ask you this. Do you 15 believe that it's important for a mesh to 16 have a pore size of 1 millimeter or greater 17 in all directions in order for the mesh to be 18 properly incorporated into the tissues once 19 it is placed? 20 A. No, I don't think it has to be 21 exactly 1 millimeter. Neutrophils and the 22 vagina itself are much smaller than that, so 23 it doesn't need to be near that size to 24 incorporate well and to heal that well.</p>
Page 188	Page 190
<p>1 applications failure modes effects analysis 2 is? 3 A. I'm not sure. 4 Q. Do you recall if you've 5 reviewed any of those for the Gynemesh PS, 6 Prolift or Prosima device? 7 A. I'm not sure. 8 Q. Do you hold yourself out as 9 having expertise or specialized knowledge 10 regarding the type of mesh used in the 11 Prosima, Prolift -- I guess I'll say 12 Gynemesh PS device even though the mesh -- 13 that's the only thing in the Gynemesh PS 14 device is the mesh? 15 A. Could you repeat the first part 16 of the question? 17 Q. Yeah, I'll re-ask it because I 18 didn't think it through before I asked it. 19 Am I correct in that you don't 20 hold yourself out as having expertise or 21 specialized knowledge regarding the type of 22 mesh used in the Prosima or Prolift device? 23 MR. GAGE: Object to form. 24 A. No, that's incorrect because I</p>	<p>1 Because as you know, when we put it in, the 2 pores are going to deform somewhat. That's 3 to be expected. And even with that, the 4 patients clinically heal well and do well 5 with good incorporation. 6 Q. Do you believe -- you just 7 stated that you know that the mesh is at 8 times going to deform. Strike that. 9 You just stated that you know 10 at -- sometimes that the mesh is going to 11 deform. Do you believe the mesh can deform 12 to the point where the pores are too small 13 for good tissue incorporation? 14 A. No, I don't think so. I think 15 that the cells are microscopic. So they're 16 going to be able to get into -- between the 17 fibers, no matter what. 18 Q. You stated that you don't think 19 it's necessary to have a pore size of 20 1 millimeter in all directions. What pore 21 size do you think is required in order for 22 the tissue to be incorporated into the body? 23 MR. FAES: You want to take a 24 quick break? I need to run to the</p>

14 (Pages 187 to 190)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 191</p> <p>1 restroom anyway. Let's go off the 2 record. 3 (Recess Taken From 9:09 a.m. To 4 9:16 a.m.) 5 BY MR. FAES: 6 Q. Doctor, we're back on the 7 record after a short break. Are you ready to 8 proceed? 9 A. Yes. 10 Q. When we took a break, there was 11 a question pending. It looked like you were 12 looking at your report, so I'll restate it. 13 You stated that you don't think 14 it is necessary to have a pore size of 15 1 millimeter in all directions. What pore 16 size do you think is required in order for 17 tissue to be incorporated into the body in 18 pelvic organ prolapse surgery with mesh? 19 A. So the Amid classification has 20 a pore size of greater than 75 microns. 21 Q. So if I understand you 22 correctly, you're relying on the Amid 23 standard for your opinion on how large the 24 pore size needs to be?</p>	<p style="text-align: right;">Page 193</p> <p>1 MR. FAES: I'll object and move 2 to strike after the answer "thinks." 3 BY MR. FAES: 4 Q. Do you know what Ethicon -- 5 strike that. 6 Do you know whether or not 7 Ethicon scientists and engineers think that 8 the Amid standard is outdated? 9 MR. GAGE: Object to form. 10 A. I don't know what they think 11 about that. 12 BY MR. FAES: 13 Q. Do you know if -- whether or 14 not Ethicon scientists and engineers thought 15 the Amid standard was outdated as early as 16 2005? 17 MR. GAGE: Object to form. 18 A. No, I don't know about that. 19 BY MR. FAES: 20 Q. You know that the Amid standard 21 was originally developed for hernia repair. 22 Do you know whether or not the FDA told 23 Ethicon that they don't believe that they can 24 leverage their hernia experience for the</p>
<p style="text-align: right;">Page 192</p> <p>1 A. Yes. But even if it were a 2 little smaller than that, it would be fine 3 because the neutrophiles and the macro 4 fascias are much smaller than that. So even 5 if it got to a form lower than that, they 6 should be able to come in and lay down the 7 collagen and the scar tissue and incorporate 8 the mesh. 9 Q. You know that the Amid standard 10 came out in 1998, correct? 11 A. Correct. 12 Q. And you know that it was 13 originally developed for guidance in hernia 14 repair, correct? 15 A. I believe so. 16 Q. Do you know whether or not 17 Dr. Amid thinks that his standard applies to 18 the type of mesh used in pelvic organ 19 prolapse and stress urinary incontinence 20 products? 21 MR. GAGE: Object to form. 22 A. I don't know what he thinks, 23 but it's been widely adopted and utilized 24 successfully by the pelvic floor literature.</p>	<p style="text-align: right;">Page 194</p> <p>1 pelvic organ prolapse products? 2 MR. GAGE: Object to form. 3 A. I don't know about that. 4 BY MR. FAES: 5 Q. If Ethicon scientists, 6 engineers and consultants believed that the 7 pore size of the mesh in the Proxima and 8 Prolift products needed to be 1 millimeters 9 in all directions in order for proper tissue 10 integration to occur, you would disagree with 11 them, correct? 12 A. I think it doesn't have to be 13 1 millimeter. It could be smaller. But I 14 think 1 millimeter is fine. It works great. 15 Q. So is the answer to my question 16 yes, if they thought it needed to be a 17 minimum of 1 millimeter in all directions in 18 order for proper tissue integration to occur, 19 you would disagree with them? 20 A. Yes, I would disagree. 21 Q. Are you forming your opinions 22 on the assumption that the only standard for 23 pore size that matters is 75 microns? 24 A. No.</p>

15 (Pages 191 to 194)

Christina Pramudji, M.D.

Page 195	Page 197
<p>1 Q. What other pore size do you 2 think matters? 3 MR. GAGE: Object to form. 4 A. Well, I'm forming my opinion 5 based on what has been used and what works 6 and what I've seen in my clinical practice. 7 So not just on the pore size. 8 BY MR. FAES: 9 Q. But regard -- with regard to 10 the pore size which is needed for proper 11 tissue integration, is the only guideline 12 that you are relying on 75 microns? 13 A. That's the main thing I'm 14 relying on because I think that's what the 15 majority of pelvic floor science relies on. 16 Q. Is there any other numerical or 17 quantitative guideline that you're relying on 18 for the size the pores need to be in the mesh 19 in order for proper tissue integration? 20 A. Not that I can think of right 21 now. 22 Q. Have you ever specifically 23 studied the question of whether or not a 24 1-millimeter pore size under strain is of any</p>	<p>1 some follow-up questions, but I think you 2 answered the question. 3 A. Okay. 4 Q. Would you agree that even if 5 the Prosima or Prolift device is placed 6 perfectly by the surgeon, that the pore sizes 7 can still become deformed or stretch or be 8 put under strain? 9 A. Yes, they can. 10 Q. Does the -- do you know if the 11 term "scar plating" had any significance for 12 Ethicon internally among doctors and 13 scientists? 14 MR. GAGE: Object to form. 15 A. I don't know. 16 BY MR. FAES: 17 Q. Would you agree that when the 18 mesh goes through the process of creating 19 scar tissue and fibrosis on the mesh, those 20 processes can also be accompanied by 21 contraction of the mesh? 22 MR. GAGE: Object to form. 23 A. It's designed to have fibrosis 24 and scarring to incorporate the mesh and</p>
Page 196	Page 198
<p>1 significance with the Prosima, Gynemesh PS or 2 Prolift devices? 3 A. Did you say "under strain"? 4 Q. Yeah, I'll re-ask the question. 5 Have you ever specifically studied the 6 question of whether or not a 1-millimeter 7 pore size under strain is of any significance 8 with the Prosima, Gynemesh PS or Prolift 9 devices? 10 A. What do you mean by "under 11 strain"? 12 Q. I mean when the mesh is put -- 13 placed under stress or deforms. 14 A. I believe I did look at some 15 articles that look at that and look at the -- 16 what happens to the pore sizes when they are 17 under strain. Whether that applies to 18 clinical practice or not, I don't think so. 19 There's going to a little bit of strain and 20 deforming, but if the mesh is placed properly 21 without tension, then the pore sizes will be 22 minimally deformed. Does that answer your 23 question? 24 Q. Yeah, I think so. Might have</p>	<p>1 you'll have some mesh contraction, but again, 2 I dispute the term "mesh" -- you'll have scar 3 contraction, but I dispute the term "mesh 4 contraction." 5 BY MR. FAES: 6 Q. So you dispute the term "mesh 7 contraction" even though the Gynemesh PS IFU 8 specifically warns excessive contraction or 9 shrinkage of the tissue surrounding the mesh 10 as a potential adverse event in the 11 Gynemesh PS? 12 MR. GAGE: Object to form. 13 A. It says -- again, it says, 14 "Excessive contraction or shrinkage of the 15 tissue surrounding the mesh." I think that's 16 the same thing that I said. 17 BY MR. FAES: 18 Q. But we -- as we've agreed, if 19 the tissue surrounding the mesh contracts, it 20 can take the mesh with it -- 21 A. Yes. 22 Q. -- meaning the mesh can 23 contract as well. 24 A. It's semantics. Yes, the mesh</p>

16 (Pages 195 to 198)

Christina Pramudji, M.D.

Page 199	Page 201
<p>1 can be incorporated into the scar tissue, but 2 the mesh itself is not contracting. 3 Q. Do you know who the inventor of 4 the Prosima device is? 5 A. I believe it was Dr. Marcus 6 Carey. 7 Q. Have you ever met Dr. Carey? 8 A. I don't think so. 9 Q. Do you know that -- whether or 10 not Dr. Carey receives royalties each time 11 the Prosima device is sold? 12 A. I don't know. 13 Q. So I take it since you don't 14 know whether or not he receives royalties, 15 you don't know how much he's been paid in 16 royalties with regard to the Prosima? 17 A. No. But he should get paid 18 because it's a great invention. He should 19 get paid for his intellectual knowledge -- 20 his intellectual property, I should say. 21 MR. FAES: Object and move to 22 strike after the answer "no." 23 BY MR. FAES: 24 Q. Do you know if he's been paid</p>	<p>1 Q. Do you know that some other 2 investigators in that study reported a zero 3 percent success rate with the Prosima at 4 their site? 5 A. No, I'm not aware of that. 6 Q. Do you think the fact that 7 Dr. Carey was the inventor of the product and 8 was going to receive royalties for each 9 Prosima device that he sold injected bias 10 into the study where he was the lead 11 investigator? 12 A. I think every investigator has 13 a bias. So, yes, of course, he's going to 14 have his own bias. 15 Q. Do you know whether or not 16 Ethicon believed that there was a fair amount 17 of spin going on regarding Dr. Carey's 18 reporting of his data? 19 A. I don't know. 20 MR. GAGE: Object to form. 21 BY MR. FAES: 22 Q. Have you ever seen any 23 documents or correspondence between Ethicon 24 indicating that that was the case?</p>
Page 200	Page 202
<p>1 over \$2 million in royalties for the Prosima 2 device? 3 MR. GAGE: Object to form. 4 A. I don't know. 5 BY MR. FAES: 6 Q. Do you know he was the lead 7 author on the Prosima study done by Ethicon 8 prior to launch? 9 A. Yes. 10 Q. Do you know what his personal 11 success rate that he reported with the 12 Prosima was in that clinical study at his 13 site? 14 A. At his site alone? 15 Q. Yes. 16 A. No, I don't know. 17 Q. Do you know if it was 18 100 percent? Would that -- would you be 19 surprised to learn that he -- strike that. 20 Would you be surprised to learn 21 that Dr. Carey reported a 100 percent success 22 rate with the Prosima at his site? 23 A. No. It could be possible based 24 on patient selection.</p>	<p>1 A. I don't recall having seen 2 that. 3 Q. Now, you've stated that you 4 don't believe that shrinkage of the mesh 5 occurs; it's contraction of the tissues 6 surrounding the mesh, correct? 7 A. Correct. 8 Q. Are you familiar with the 9 Fatton article, which I believe is cited in 10 your reliance materials? 11 A. How are you spelling that? 12 Q. F-a-t-t-o-n. 13 A. I would have to review it 14 again. Not off the top of my head. 15 Q. Well, let me ask you this. Do 16 you recall in that study that they reported a 17 17 percent shrinkage rate at three months? 18 A. I would have to look at it. 19 Q. So you don't recall as you sit 20 here today? 21 A. I don't recall. 22 Q. Would you agree that -- 23 assuming they did report a 17 percent 24 shrinkage rate at three months, that that's a</p>

17 (Pages 199 to 202)

Christina Pramudji, M.D.

Page 203	Page 205
<p>1 significant shrinkage rate?</p> <p>2 MR. GAGE: Object to form.</p> <p>3 A. I would say that that is within</p> <p>4 the norm for pelvic surgery to have</p> <p>5 17 percent shrinkage of the scar tissue. You</p> <p>6 would want to have some shrinkage of the scar</p> <p>7 tissue in order to have a good repair. And</p> <p>8 17 percent sounds reasonable to me.</p> <p>9 BY MR. FAES:</p> <p>10 Q. But would you agree that a</p> <p>11 17 percent shrinkage rate is clinically</p> <p>12 significant and could have clinical impact to</p> <p>13 the patient?</p> <p>14 A. Yes, I think it would have a</p> <p>15 good clinical impact because they're going to</p> <p>16 have better support and -- better support of</p> <p>17 the vaginal wall.</p> <p>18 Q. So you believe that -- do you</p> <p>19 believe that shrinkage of the mesh or</p> <p>20 contraction of the tissue surrounding the</p> <p>21 mesh is a positive thing?</p> <p>22 A. Yes. It's desirable.</p> <p>23 Q. Do you believe that's true in</p> <p>24 all cases, or do you believe that there's</p>	<p>1 through things.</p> <p>2 Q. Have you relied on data and</p> <p>3 literature published by Dr. Cosson and the</p> <p>4 TVM group to support your opinions that the</p> <p>5 Prolift and Gynemesh PS is safe and</p> <p>6 effective?</p> <p>7 A. Yes.</p> <p>8 Q. Do you know whether or not</p> <p>9 Dr. Cosson is considered the inventor of the</p> <p>10 Prolift?</p> <p>11 A. I believe he is.</p> <p>12 Q. Have you ever met Dr. Cosson?</p> <p>13 A. No.</p> <p>14 Q. Never been to France?</p> <p>15 A. No.</p> <p>16 Q. Do you know if Dr. Cosson</p> <p>17 receives royalty on the Prolift like</p> <p>18 Dr. Carey?</p> <p>19 A. I don't know.</p> <p>20 Q. Do you know if Dr. Cosson has</p> <p>21 also received over \$2 million in royalties</p> <p>22 for the Prolift device?</p> <p>23 A. I don't know.</p> <p>24 Q. Would you agree that the fact</p>
Page 204	Page 206
<p>1 instances where contraction or shrinkage of</p> <p>2 the mesh can cause pain or can cause the</p> <p>3 device to migrate?</p> <p>4 A. Oh, yes, I think it's clear</p> <p>5 that you're going to have some patients that</p> <p>6 heal with exuberant scar tissue, nerve</p> <p>7 endings get involved and they would have more</p> <p>8 pain. That can also occur with plication or</p> <p>9 sacrospinous ligament fixation or uterosacral</p> <p>10 ligament fixation, so it's not unique to</p> <p>11 mesh.</p> <p>12 MR. FAES: I'm going to object</p> <p>13 and move to strike after the answer</p> <p>14 ending with "pain." I didn't ask</p> <p>15 about plication or sacrospinous</p> <p>16 ligament fixation or any of that.</p> <p>17 BY MR. FAES:</p> <p>18 Q. Are you aware of any clinical</p> <p>19 data reported by the French transvaginal mesh</p> <p>20 group regarding the percentage of women</p> <p>21 treated with Prolift suffering from painful</p> <p>22 mesh contraction with the Prolift?</p> <p>23 A. I believe I've seen that. I</p> <p>24 can't cite it right now without looking</p>	<p>1 that Dr. Cosson was the inventor and received</p> <p>2 royalties, that that would inject potential</p> <p>3 bias into any study he was involved in?</p> <p>4 A. I would give the same answer</p> <p>5 before, that every investigator has some bias</p> <p>6 to some degree. So I would not be surprised</p> <p>7 if there were some bias there.</p> <p>8 Q. So is the answer to my question</p> <p>9 yes, you would agree that Dr. Cosson would</p> <p>10 have potential bias in any reporting of any</p> <p>11 studies that he was involved in with the</p> <p>12 Prolift?</p> <p>13 A. Yes, there's a potential for</p> <p>14 bias there.</p> <p>15 Q. Are you familiar with committee</p> <p>16 opinion 513, the joint opinion of ACOG and</p> <p>17 AUGS?</p> <p>18 A. Can I take a look at it?</p> <p>19 Q. I don't have -- I don't have a</p> <p>20 copy with me here. I'm just asking you, are</p> <p>21 you familiar with it?</p> <p>22 A. I don't know of one by name --</p> <p>23 by that name.</p> <p>24 Q. Okay. Well, I'll represent to</p>

18 (Pages 203 to 206)

Christina Pramudji, M.D.

Page 207	Page 209
<p>1 you that a portion of the committee opinion 2 said that the mesh kit should only be used in 3 high -- strike that. 4 I'll represent to you that a 5 portion of the committee opinion says that 6 mesh kits should only be used in high-risk 7 individuals for which no other options are 8 available or appropriate. 9 Do you agree or disagree with 10 that opinion? 11 MR. GAGE: Object to form. 12 A. At this point I would agree, 13 given the current legal environment, I think, 14 although we had great success in patients 15 that weren't as high risk or that was their 16 first option. But unfortunately in this 17 current legal environment, I would have to 18 agree with that statement. 19 BY MR. FAES: 20 Q. You say "in this current 21 environment." At what point do you 22 believe -- strike that. 23 You indicated -- is there -- 24 strike that too.</p>	<p>1 judgment, you disagree with that opinion? 2 A. Right. Based on my medical 3 judgment, I still think that transvaginal 4 mesh repairs are very effective, very safe 5 and very beneficial to women, even if they're 6 not high risk, even if they haven't failed a 7 prior procedure. And that's based on the 8 literature and based on my own experience. 9 Q. Is the -- as you called it, the 10 legal environment the only reason why you 11 agree with that opinion today? 12 A. Yes. 13 Q. So the recent FDA actions and 14 reclassifying pelvic organ prolapse products 15 to a class III high-risk device and issuing a 16 public health notification in 2008 and 2011 17 have no bearing on that opinion? 18 A. No. 19 Q. Do you agree that the Prolift 20 should only be used in women for whom other 21 approaches and other alternative approaches 22 are not reasonable? I think I asked a bad 23 question. I'm going to strike that and 24 re-ask it.</p>
Page 208	Page 210
<p>1 Is there a point at which you 2 would not have agreed with that opinion, a 3 point in time, and when did that -- when did 4 your opinion change that you agree with the 5 opinion? 6 A. Probably around the time that 7 there started to be a lot of attorney 8 advertising, soliciting patients, that 9 created a negative environment around mesh 10 surgery. So I think that was 2012, somewhere 11 around there. 12 Q. So up until 2012 you would have 13 disagreed with that opinion; is that 14 accurate? 15 A. That's correct. 16 Q. And after 2012 you agree with 17 that opinion? 18 A. To a degree, yes. 19 Q. Is it your testimony that you 20 only agree with that opinion now because of 21 the legal environment? 22 A. That's correct. 23 Q. So it's not based on medical 24 judgment on your -- based on your medical</p>	<p>1 Do you agree that the Prolift 2 should only be used in women for whom other 3 alternative approaches are not reasonable? 4 MR. GAGE: Object to form. 5 A. Well, the Prolift isn't 6 available anymore, so I'm not sure how to 7 answer that question. 8 BY MR. FAES: 9 Q. When the Prolift was available, 10 would you agree that it should have only been 11 used in women for whom other alternative 12 approaches are not reasonable? 13 A. No. 14 Q. Same question on the Prosima? 15 A. No. I feel like I was asked a 16 lot of these questions before in the Prolift 17 deposition. 18 Q. You've stated some questions -- 19 stated some opinions about the current legal 20 environment regarding mesh devices and 21 products. Do you know how many mesh lawsuits 22 have been filed in the United States at this 23 point? 24 A. I don't know the number.</p>

19 (Pages 207 to 210)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 211</p> <p>1 Q. Do you believe that all of the</p> <p>2 mesh suits filed in this country are</p> <p>3 unfounded?</p> <p>4 A. That all of them are unfounded?</p> <p>5 Well, based on the claims of mesh defect and</p> <p>6 failure to warn, I would say yes because</p> <p>7 there's not a mesh defect; there's not a</p> <p>8 failure to warn.</p> <p>9 Q. So if there were over 70,000</p> <p>10 individuals in the United States that had</p> <p>11 filed legal claims against the manufacturers</p> <p>12 of mesh products, you believe that all of</p> <p>13 those claims are unfounded?</p> <p>14 A. Based on the claims, yes.</p> <p>15 Q. Do you -- you would agree that</p> <p>16 the Prosima device is supposed to be placed</p> <p>17 without tension; is that correct?</p> <p>18 A. That's correct.</p> <p>19 Q. Do you know what Ethicon</p> <p>20 thought as to whether or not most doctors</p> <p>21 understood the tension-free concept in</p> <p>22 connection with the Prosima?</p> <p>23 MR. GAGE: Object to form.</p> <p>24 A. No, I don't know what they</p>	<p style="text-align: right;">Page 213</p> <p>1 Q. Let me ask a different</p> <p>2 question. Would you agree that if the</p> <p>3 tension-free concept was not understood and</p> <p>4 mesh ended up under tension after completion</p> <p>5 of the Prosima procedure, that could increase</p> <p>6 the risk of complications, correct?</p> <p>7 A. That could, yes.</p> <p>8 Q. Could it increase the risk of</p> <p>9 treatment failure?</p> <p>10 A. No. I think the risk that I</p> <p>11 think of is potentially pulling on the tissue</p> <p>12 and the scarring pulling and causing pain.</p> <p>13 That's the issue I think of with tension.</p> <p>14 Q. Would you agree that even if a</p> <p>15 doctor is fully trained and follows the</p> <p>16 Prosima technique perfectly, he can end up</p> <p>17 with tension on the mesh that can lead to</p> <p>18 complications?</p> <p>19 A. That -- yes, that can occur.</p> <p>20 The patient can wake up and cough and that</p> <p>21 can pull things, or the way that they heal,</p> <p>22 they have exuberant scar tissue and that can</p> <p>23 cause tension.</p> <p>24 Q. Are you aware of any monograph</p>
<p style="text-align: right;">Page 212</p> <p>1 thought.</p> <p>2 BY MR. FAES:</p> <p>3 Q. Do you know what Ethicon</p> <p>4 thought as to whether or not most doctors</p> <p>5 understood the vaginal support device concept</p> <p>6 in connection with the Prosima?</p> <p>7 MR. GAGE: Object to form.</p> <p>8 A. No, I don't know what they</p> <p>9 thought.</p> <p>10 BY MR. FAES:</p> <p>11 Q. And you don't know whether or</p> <p>12 not most doctors understood it or not; is</p> <p>13 that correct?</p> <p>14 A. Right, I couldn't comment on</p> <p>15 that.</p> <p>16 Q. You would agree that if the</p> <p>17 tension-free concept with the Prosima was not</p> <p>18 understood and mesh ended up under tension</p> <p>19 after the procedure, that could increase the</p> <p>20 risk of erosions, right?</p> <p>21 A. No, I wouldn't say that. I</p> <p>22 don't think that that would cause erosion.</p> <p>23 Erosion occurs when the mesh is not placed in</p> <p>24 the proper plane.</p>	<p style="text-align: right;">Page 214</p> <p>1 for the Prosima device like there is for the</p> <p>2 Prolift device?</p> <p>3 A. I can't recall if I have seen</p> <p>4 that or not.</p> <p>5 Q. Same question with regard to</p> <p>6 the Gynemesh PS. Is there a Gynemesh PS</p> <p>7 surgeon resource monograph like there is for</p> <p>8 the Prolift and TVT?</p> <p>9 A. I can't recall.</p> <p>10 Q. But there is professional</p> <p>11 education materials for the Prosima device,</p> <p>12 correct?</p> <p>13 A. That's correct.</p> <p>14 Q. Do you recall if there's</p> <p>15 professional education materials for the</p> <p>16 Gynemesh PS device?</p> <p>17 A. Not that I'm aware of.</p> <p>18 Q. Is it your opinion that a</p> <p>19 monograph or professional education materials</p> <p>20 can be a substitute for the IFU in providing</p> <p>21 information about risks and complications to</p> <p>22 physicians?</p> <p>23 A. Yes, I believe so.</p> <p>24 Q. Do you know if -- under the</p>

20 (Pages 211 to 214)

Christina Pramudji, M.D.

Page 215	Page 217
<p>1 federal rules or regulatory guidance if 2 Ethicon is allowed to provide that kind of 3 information in a source other than the IFU 4 such as a monograph or professional education 5 materials? 6 A. I don't know about that. 7 Q. Would you agree that unlike the 8 IFU, Ethicon can't ensure that the monographs 9 or the professional education materials reach 10 every physician that uses the product? 11 MR. GAGE: Object to form. 12 A. Can you repeat that question, 13 please. 14 BY MR. FAES: 15 Q. Would you agree that unlike the 16 IFU, Ethicon has no way of ensuring that 17 monographs or professional education 18 materials reach every physician that uses the 19 product? 20 A. I don't think they can ensure 21 that the IFU reaches every physician. Sure, 22 it's in every product, but that doesn't mean 23 that every physician does look at it or read 24 it.</p>	<p>1 Q. Once an IFU is out there, if 2 Ethicon learns of a risk or complication that 3 was not previously warned about and it was a 4 significant risk or complication in terms of 5 the harm it could cause to a woman, do you 6 know whether or not Ethicon had any 7 obligation to get that out to doctors? 8 A. Could you repeat that, please. 9 Q. Sure. Once an IFU is out 10 there, if Ethicon learns of a risk or 11 complication that was not previously warned 12 about and it's a significant risk or 13 complication in terms of the harm it could 14 cause to a woman, do you know whether or not 15 Ethicon had any obligation to get that out to 16 doctors? 17 MR. GAGE: Object to form. 18 A. I don't know. 19 BY MR. FAES: 20 Q. I just want to backtrack a 21 little bit on the IFU -- the 2015 Gynemesh 22 IFU that was put out there. 23 Do you think it would have been 24 reasonable for Ethicon to send a letter, a</p>
Page 216	Page 218
<p>1 Q. But by placing the IFU in the 2 box, Ethicon ensures that every physician has 3 at least access to the IFU, correct? 4 A. Yes, I can agree with that. 5 Q. If Ethicon had put the same 6 information that's in the monograph in their 7 professional education materials in the IFU 8 with regards to the risks of the device, they 9 could have ensured that every physician who 10 implants the device at least has access to 11 that information, correct? 12 A. I'm sorry, can you repeat the 13 question? 14 Q. If Ethicon had put the same 15 information in the monograph -- strike that. 16 If Ethicon had put the same 17 information that's in the monograph and 18 professional educations in their IFU with 19 regard to the risks and adverse reactions of 20 the device, they could have ensured that 21 every physician who implants the device at 22 least has access to that information, 23 correct? 24 A. Sure.</p>	<p>1 "Dear Doctor" letter out to physicians when 2 they put that IFU out telling them that, hey, 3 we've added some adverse reactions to this 4 IFU that were not previously in the IFU? 5 A. Sure, I think that's 6 reasonable. I don't think it's necessary, 7 but it's reasonable. 8 Q. Do you know whether or not that 9 occurred? 10 A. I don't know. 11 Q. Do you think it would have been 12 reasonable in 2013 for Ethicon to send a 13 letter out to physicians that -- informing 14 them that, hey, we've changed the indications 15 for use for this mesh so that it is no longer 16 indicated for transvaginal mesh placement? 17 Do you think that would be reasonable? 18 A. Sure, I think it's reasonable. 19 Q. Do you think it would have been 20 reasonable for them in this letter to also 21 tell physicians that the only reason that the 22 FDA is still allowing this product to be sold 23 is because it agreed to remove the 24 transvaginal indication and change the</p>

21 (Pages 215 to 218)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 219</p> <p>1 indication to only be placed abdominally?</p> <p>2 MR. GAGE: Object to form.</p> <p>3 A. I don't think that's reasonable</p> <p>4 or necessary. That sounds excessive to me.</p> <p>5 BY MR. FAES:</p> <p>6 Q. You don't think a reasonable</p> <p>7 physician would want to know that the only</p> <p>8 reason the FDA is still allowing the</p> <p>9 Gynemesh PS to be sold is because Ethicon</p> <p>10 agreed to remove the transvaginal use</p> <p>11 indication from the IFU?</p> <p>12 MR. GAGE: Object to form.</p> <p>13 A. I don't think so.</p> <p>14 BY MR. FAES:</p> <p>15 Q. Do you know whether or not</p> <p>16 Ethicon did indeed send out a letter to</p> <p>17 physicians informing them that the</p> <p>18 indications for use for the Gynemesh PS</p> <p>19 device changed?</p> <p>20 A. I don't know.</p> <p>21 Q. Do you think it would be</p> <p>22 reasonable for Ethicon to put some kind of an</p> <p>23 indication on the Gynemesh PS box that</p> <p>24 contains the device either with a call-out on</p>	<p style="text-align: right;">Page 221</p> <p>1 would be a mistake to launch the device onto</p> <p>2 the market, do you think it would be wrongful</p> <p>3 for the company to launch that device anyway</p> <p>4 if the motivation is only to make a profit?</p> <p>5 MR. GAGE: Object to form.</p> <p>6 A. Can you repeat that question,</p> <p>7 please.</p> <p>8 BY MR. FAES:</p> <p>9 Q. Sure. If the overall consensus</p> <p>10 among a medical device company's expert is</p> <p>11 that it would be a mistake to launch that</p> <p>12 device onto the market, do you think it would</p> <p>13 be wrongful for the company to launch that</p> <p>14 device anyway if the only motivation is to</p> <p>15 make a profit?</p> <p>16 MR. GAGE: Object to form.</p> <p>17 A. Well, it depends on why they</p> <p>18 think it's a mistake. I mean, obviously the</p> <p>19 purpose of corporations is they have to make</p> <p>20 a profit with whatever they do. So it</p> <p>21 depends on what the -- why -- what they're --</p> <p>22 why they're saying it's a mistake.</p> <p>23 BY MR. FAES:</p> <p>24 Q. If the company's experts</p>
<p style="text-align: right;">Page 220</p> <p>1 the box or a sticker informing physicians</p> <p>2 that, hey, the indications for this use have</p> <p>3 changed; you might want to read them? Do you</p> <p>4 think that would be reasonable?</p> <p>5 MR. GAGE: Object to form.</p> <p>6 A. Again, I think it's reasonable,</p> <p>7 but it's not necessary.</p> <p>8 BY MR. FAES:</p> <p>9 Q. So even though that you -- even</p> <p>10 though you've testified that you don't</p> <p>11 generally review the IFU, again, once you've</p> <p>12 used a product for the first time, you don't</p> <p>13 believe it's necessary?</p> <p>14 A. Correct.</p> <p>15 Q. You don't think that that's</p> <p>16 something that physicians would want to know</p> <p>17 or have their attention drawn to, that, hey,</p> <p>18 the indications for this device may have</p> <p>19 changed since the last time you used it?</p> <p>20 A. I can -- I can't speak for all</p> <p>21 physicians. I'm speaking for myself. That</p> <p>22 for me, it wouldn't be necessary.</p> <p>23 Q. If the overall consensus among</p> <p>24 a medical devices company's expert is that it</p>	<p style="text-align: right;">Page 222</p> <p>1 believe it's a mistake to launch that</p> <p>2 particular device on the market because it is</p> <p>3 not more safe or effective than alternative</p> <p>4 treatment options, do you think it would be</p> <p>5 wrongful for the company to launch that</p> <p>6 device anyway?</p> <p>7 A. I can't answer that yes or no.</p> <p>8 It really depends on the details of the</p> <p>9 product. There may be some other advantages,</p> <p>10 some other factors involved.</p> <p>11 Q. If the overall consensus about</p> <p>12 a medical device -- strike that.</p> <p>13 If the overall consensus among</p> <p>14 the medical device company's experts is that</p> <p>15 it would be a mistake to launch a particular</p> <p>16 device onto the market, do you think the</p> <p>17 doctors and patients who are sold that device</p> <p>18 should know that information?</p> <p>19 A. I think it's more -- no,</p> <p>20 because I think it's more important that</p> <p>21 there's data showing the results, that</p> <p>22 there's studies that show the results of what</p> <p>23 happened and not their -- just those</p> <p>24 opinions.</p>

22 (Pages 219 to 222)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 223</p> <p>1 Q. So you don't think that that's</p> <p>2 information that doctors or patients would</p> <p>3 want to know, is that the company had asked</p> <p>4 their experts what they thought about the</p> <p>5 device and the experts told the company, this</p> <p>6 is a big mistake, don't do it?</p> <p>7 MR. GAGE: Object to form.</p> <p>8 A. I don't know what other doctors</p> <p>9 and patients would want to know.</p> <p>10 BY MR. FAES:</p> <p>11 Q. Do you know whether scar</p> <p>12 contracture around the mesh can occur with</p> <p>13 the Gynemesh PS?</p> <p>14 A. Yes, it can. As in every</p> <p>15 pelvic surgery, there's going to be scar</p> <p>16 contracture if you just cut on the vagina.</p> <p>17 MR. FAES: Object and move to</p> <p>18 strike after the answer "yes, it can."</p> <p>19 BY MR. FAES:</p> <p>20 Q. Do you know whether or not that</p> <p>21 was a problem that Ethicon's engineers were</p> <p>22 trying to solve by designing a better mesh?</p> <p>23 A. I don't recall.</p> <p>24 Q. Would you agree that scar</p>	<p style="text-align: right;">Page 225</p> <p>1 A. Yes, it can do that with or</p> <p>2 without mesh.</p> <p>3 MR. FAES: Object and move to</p> <p>4 strike after the answer "yes."</p> <p>5 BY MR. FAES:</p> <p>6 Q. Would you agree that scar</p> <p>7 contracture can cause erosion?</p> <p>8 A. No.</p> <p>9 Q. Would you agree that scar</p> <p>10 contracture can cause discomfort during sex?</p> <p>11 A. Yes. That can occur with or</p> <p>12 without the presence of mesh.</p> <p>13 MR. FAES: Object and move to</p> <p>14 strike after the answer "yes."</p> <p>15 BY MR. FAES:</p> <p>16 Q. So you disagree that scar</p> <p>17 contracture can cause recurrence of the</p> <p>18 prolapse or erosion, correct?</p> <p>19 A. That's correct.</p> <p>20 Q. So if physicians were reporting</p> <p>21 to Ethicon that scar contracture can cause</p> <p>22 recurrence of the prolapse and erosion, you</p> <p>23 would disagree with those physicians?</p> <p>24 A. Yes.</p>
<p style="text-align: right;">Page 224</p> <p>1 contracture can translate into procedural</p> <p>2 complications?</p> <p>3 A. Yes, it can.</p> <p>4 Q. Do you know whether or not in</p> <p>5 2005, physicians were asking Ethicon for a</p> <p>6 mesh which would be better than the</p> <p>7 Gynemesh PS in the area of scar contracture?</p> <p>8 A. I don't know.</p> <p>9 Q. Would you agree that scar</p> <p>10 contracture can cause recurrence of prolapse?</p> <p>11 A. No, I disagree with that.</p> <p>12 Q. Would you agree that scar</p> <p>13 contracture can cause pain?</p> <p>14 A. Yes, I agree with that.</p> <p>15 Q. Would you agree that scar</p> <p>16 contracture can cause stiffness?</p> <p>17 A. Stiffness?</p> <p>18 Q. Yes. Stiffness of the mesh.</p> <p>19 I'll rephrase. Would you agree that scar</p> <p>20 contracture can cause stiffness of the mesh?</p> <p>21 A. No, I don't think it causes</p> <p>22 stiffness of the mesh.</p> <p>23 Q. Would you agree that scar</p> <p>24 contracture can cause a stiff scar tissue?</p>	<p style="text-align: right;">Page 226</p> <p>1 Q. Would you agree that for mesh</p> <p>2 to be successfully used for the treatment of</p> <p>3 pelvic organ prolapse, it should be soft and</p> <p>4 compliant with a woman's vaginal tissues?</p> <p>5 A. Ideally, yes.</p> <p>6 Q. Would you agree that a mesh</p> <p>7 could be too stiff for the treatment of</p> <p>8 pelvic organ prolapse?</p> <p>9 A. Yes, it's possible.</p> <p>10 MR. FAES: Can we go off the</p> <p>11 record for a quick second.</p> <p>12 (Recess Taken From 10:00 a.m.</p> <p>13 To 10:09 a.m.)</p> <p>14 BY MR. FAES:</p> <p>15 Q. Dr. Pramudji, we're back on the</p> <p>16 record after a short break. Are you ready to</p> <p>17 proceed?</p> <p>18 A. Yes.</p> <p>19 Q. You know that the Gynemesh PS</p> <p>20 is, in fact, less stiff than the traditional</p> <p>21 Prolene mesh used for hernia repairs,</p> <p>22 correct?</p> <p>23 A. Yes.</p> <p>24 Q. And, in fact, that's a positive</p>

23 (Pages 223 to 226)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 227</p> <p>1 thing --</p> <p>2 A. Yes.</p> <p>3 Q. -- you would agree --</p> <p>4 A. Yes.</p> <p>5 Q. -- for use in vaginal tissues,</p> <p>6 correct?</p> <p>7 A. Yes, I agree.</p> <p>8 Q. Have you ever considered using</p> <p>9 traditional Prolene mesh for the treatment of</p> <p>10 pelvic organ prolapse?</p> <p>11 A. No.</p> <p>12 Q. Have you ever considered using</p> <p>13 traditional Prolene mesh for use in vaginal</p> <p>14 tissues?</p> <p>15 A. No.</p> <p>16 Q. Would you ever consider using</p> <p>17 it?</p> <p>18 A. I don't think so.</p> <p>19 Q. Would you never -- not consider</p> <p>20 using it because it's generally too stiff to</p> <p>21 be compliant with vaginal tissues?</p> <p>22 A. That's correct.</p> <p>23 Q. Would you agree that clinically</p> <p>24 there may be an impact with increased</p>	<p style="text-align: right;">Page 229</p> <p>1 Gynemesh PS is an appropriate stiffness of</p> <p>2 mesh, but I wouldn't disagree with trying to</p> <p>3 make a less stiff mesh and see if it</p> <p>4 behaved -- if the results are as good.</p> <p>5 Q. Do you know whether or not, as</p> <p>6 of 2009, it was Ethicon's goal that all</p> <p>7 future meshes developed by Ethicon for pelvic</p> <p>8 organ prolapse should be less rigid than the</p> <p>9 Gynemesh PS?</p> <p>10 MR. GAGE: Object to form.</p> <p>11 A. I don't know.</p> <p>12 BY MR. FAES:</p> <p>13 Q. Would you agree that clinical</p> <p>14 trials show that large-pore meshes in general</p> <p>15 provide better patient comfort than standard</p> <p>16 meshes?</p> <p>17 MR. GAGE: Object to form.</p> <p>18 BY MR. FAES:</p> <p>19 Q. Strike that. I'm going to</p> <p>20 withdraw that and ask a different question.</p> <p>21 Would you agree that clinical</p> <p>22 trials show in general that large-pore meshes</p> <p>23 provide better patient comfort than standard</p> <p>24 meshes and that the reason for that is due to</p>
<p style="text-align: right;">Page 228</p> <p>1 rigidity with any given mesh as it may</p> <p>2 increase vaginal stiffness postoperatively</p> <p>3 with a potential to impair sexual function?</p> <p>4 A. Could you repeat that, please.</p> <p>5 Q. Sure. Would you agree that</p> <p>6 clinically there may be an impact of</p> <p>7 increased rigidity with any given mesh as it</p> <p>8 may increase vaginal stiffness</p> <p>9 postoperatively with a potential to impair</p> <p>10 sexual function?</p> <p>11 MR. GAGE: Object to form.</p> <p>12 A. That could occur with some</p> <p>13 meshes that are more stiff.</p> <p>14 BY MR. FAES:</p> <p>15 Q. Would you agree that any future</p> <p>16 meshes developed by Ethicon for the treatment</p> <p>17 of pelvic organ prolapse should be less rigid</p> <p>18 than the Gynemesh PS?</p> <p>19 A. No, I don't agree with that.</p> <p>20 Q. So if Ethicon's medical</p> <p>21 directors believe that that was an</p> <p>22 appropriate goal, you would disagree with</p> <p>23 them?</p> <p>24 A. I would say that the</p>	<p style="text-align: right;">Page 230</p> <p>1 lower scar tissue formation and lower</p> <p>2 stiffness?</p> <p>3 MR. GAGE: Object to form.</p> <p>4 A. What are the standard meshes</p> <p>5 that you're referring to?</p> <p>6 BY MR. FAES:</p> <p>7 Q. A standard mesh would be, for</p> <p>8 example, the standard Prolene mesh or the</p> <p>9 standard Marlex mesh, which is now called the</p> <p>10 Bard mesh.</p> <p>11 A. Okay. I understand. So the</p> <p>12 answer -- you'd better repeat the question so</p> <p>13 I make sure I answer properly.</p> <p>14 Q. Sure. Would you agree that</p> <p>15 clinical trials show that large-pore meshes</p> <p>16 provide better patient comfort than standard</p> <p>17 meshes and the reason is due to lower scar</p> <p>18 tissue formation and lower stiffness?</p> <p>19 A. Yes, that's correct.</p> <p>20 Q. Are you aware that Ethicon was</p> <p>21 told by its top consultants that it didn't</p> <p>22 make sense to use the Prosima in people with</p> <p>23 lesser degrees of prolapse given the</p> <p>24 outcomes?</p>

24 (Pages 227 to 230)

Christina Pramudji, M.D.

Page 231	Page 233
<p>1 MR. GAGE: Object to form.</p> <p>2 A. I'm not aware of that.</p> <p>3 BY MR. FAES:</p> <p>4 Q. Do you know how the mesh in the</p> <p>5 Prolift is cut?</p> <p>6 A. I believe it's machine cut.</p> <p>7 Q. You believe that the mesh in</p> <p>8 the Prolift is machine cut?</p> <p>9 A. Yes.</p> <p>10 Q. Do you know how the mesh in the</p> <p>11 Prosima is cut?</p> <p>12 A. I believe it's also machine</p> <p>13 cut.</p> <p>14 Q. Do you know how the mesh in the</p> <p>15 Gynemesh PS flat sheets is cut?</p> <p>16 A. Not sure about that one.</p> <p>17 Q. Do you know whether or not the</p> <p>18 cutting method for Prolene mesh affects the</p> <p>19 rigidity or stiffness of the mesh?</p> <p>20 A. It does not.</p> <p>21 Q. So it's your opinion that -- to</p> <p>22 a reasonable degree of medical certainty,</p> <p>23 that the cutting method for the Prolene mesh,</p> <p>24 whether it be mechanical, laser cut or</p>	<p>1 whether it's the Prolift, the Prosima or the</p> <p>2 flat sheets, that there can be sharp edges</p> <p>3 after the mesh is cut?</p> <p>4 MR. GAGE: Object to form.</p> <p>5 A. No, they're not sharp edges.</p> <p>6 They're floppy fibers.</p> <p>7 BY MR. FAES:</p> <p>8 Q. So you don't believe that there</p> <p>9 can be a sharp edge on the Gynemesh PS mesh</p> <p>10 after it's cut with scissors?</p> <p>11 A. No, no sharper than a suture</p> <p>12 that you would have.</p> <p>13 Q. You don't believe that a</p> <p>14 potential risk -- strike that.</p> <p>15 You don't believe that there</p> <p>16 can be a sharp edge after cutting the</p> <p>17 Gynemesh PS with the scissors and the</p> <p>18 potential risk of that sharp edge is that it</p> <p>19 can cause erosion or pain or protrude through</p> <p>20 the woman's delicate vaginal tissues; is that</p> <p>21 correct?</p> <p>22 A. That's correct.</p> <p>23 Q. And if Ethicon scientists and</p> <p>24 engineers who were assessing the risks of the</p>
Page 232	Page 234
<p>1 ultrasonically cut, has no effect on the</p> <p>2 stiffness or rigidity of the mesh?</p> <p>3 A. That's correct.</p> <p>4 Q. Have you seen any studies that</p> <p>5 Ethicon has done with regard to the</p> <p>6 difference in stiffness between</p> <p>7 ultrasonically cut and laser cut mesh?</p> <p>8 A. Not that I can recall, as I sit</p> <p>9 here right now.</p> <p>10 Q. If Ethicon did a study</p> <p>11 comparing ultrasonically cut mesh to laser</p> <p>12 cut mesh and found that one of those meshes</p> <p>13 was stiffer than the other, you would</p> <p>14 disagree with those findings?</p> <p>15 MR. GAGE: Object to form.</p> <p>16 A. I would -- I would have to look</p> <p>17 at it, but I don't think it would make any</p> <p>18 clinical difference at all, because half the</p> <p>19 time you end up trimming the edges anyway,</p> <p>20 which is where the cut edge is. So it ends</p> <p>21 up being mechanically cut no matter what.</p> <p>22 BY MR. FAES:</p> <p>23 Q. Would you agree that when you</p> <p>24 cut the Gynemesh PS with a pair of scissors,</p>	<p>1 Gynemesh PS mesh found that that was a</p> <p>2 potential risk, you would disagree with them?</p> <p>3 MR. GAGE: Object to form.</p> <p>4 A. Yes, I disagree with them.</p> <p>5 That's not what we see in clinical practice.</p> <p>6 BY MR. FAES:</p> <p>7 Q. If other doctors told Ethicon</p> <p>8 that they were concerned that there was a</p> <p>9 risk of sharp edges after the Gynemesh PS</p> <p>10 mesh was cut that could be sharp and cause</p> <p>11 erosion or pain or complications, you believe</p> <p>12 those doctors are wrong and their fears are</p> <p>13 unfounded?</p> <p>14 MR. GAGE: Object to form.</p> <p>15 A. I'm not sure what they're doing</p> <p>16 or how they're implanting it, but when you</p> <p>17 cut the mesh, the edges are no sharper than</p> <p>18 they were before you cut it. And the mesh</p> <p>19 itself is not going to just start poking</p> <p>20 through. Either it's not placed in the right</p> <p>21 plane or the patient has poor wound healing.</p> <p>22 It doesn't just cut through. It's not like</p> <p>23 that at all. It's soft and floppy.</p> <p>24 BY MR. FAES:</p>

25 (Pages 231 to 234)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 235</p> <p>1 Q. Okay. I'm going to have to</p> <p>2 re-ask that question because I think the</p> <p>3 answer you gave me is a little bit</p> <p>4 different --</p> <p>5 A. Sorry.</p> <p>6 Q. -- than the answer I was</p> <p>7 looking for.</p> <p>8 If other doctors told Ethicon</p> <p>9 that they were concerned about sharp edges in</p> <p>10 the Gynemesh PS after it was cut with the</p> <p>11 scissors and that those sharp edges could</p> <p>12 potentially protrude through vaginal tissue</p> <p>13 and cause pain, do you believe that those</p> <p>14 physicians' fears are unfounded?</p> <p>15 MR. GAGE: Object to form.</p> <p>16 A. Yes, I disagree with those</p> <p>17 physicians.</p> <p>18 BY MR. FAES:</p> <p>19 Q. If those same physicians were</p> <p>20 concerned that particles could be released</p> <p>21 when the Gynemesh PS was cut through</p> <p>22 scissors -- strike that.</p> <p>23 If those physicians were</p> <p>24 concerned that particles could be released</p>	<p style="text-align: right;">Page 237</p> <p>1 products?</p> <p>2 A. No, I don't have a calculated</p> <p>3 numeric rate for my patients.</p> <p>4 Q. Same question with regard to</p> <p>5 complication or erosion or extrusion rates,</p> <p>6 do you intend to offer an opinion in this</p> <p>7 case with regard to a numeric percentage of</p> <p>8 complications or erosions or extrusion rates</p> <p>9 that you've experienced personally?</p> <p>10 A. Perhaps. I have in the past</p> <p>11 calculated reoperation rates, but I can't</p> <p>12 recall right now if it was on Prolift or on</p> <p>13 TVT. I would have to go back and look at my</p> <p>14 operative logs.</p> <p>15 Q. So --</p> <p>16 A. So I may have that rate on --</p> <p>17 Q. Just reoperation rates?</p> <p>18 A. Correct, just reoperation</p> <p>19 rates.</p> <p>20 Q. Not exposure or extrusion</p> <p>21 rates?</p> <p>22 A. Correct.</p> <p>23 Q. Can you tell me how you arrived</p> <p>24 at those reoperation rates?</p>
<p style="text-align: right;">Page 236</p> <p>1 when the Gynemesh PS was cut with scissors</p> <p>2 and that those particles could become lodged</p> <p>3 in a woman's vaginal tissues and cause</p> <p>4 potential complications, do you believe those</p> <p>5 physicians' fears are unfounded?</p> <p>6 MR. GAGE: Object to form.</p> <p>7 A. Absolutely.</p> <p>8 BY MR. FAES:</p> <p>9 Q. Doctor, are you going to</p> <p>10 offer -- do you plan to offer an opinion in</p> <p>11 this case about your personal success rate</p> <p>12 with the Prosima, Prolift or Gynemesh</p> <p>13 products?</p> <p>14 A. Yes.</p> <p>15 Q. What is the opinion you intend</p> <p>16 to offer about your personal success rate</p> <p>17 with those products?</p> <p>18 A. What I found is that the</p> <p>19 products were very successful with a high</p> <p>20 patient satisfaction with few complications.</p> <p>21 Q. Do you intend to offer a</p> <p>22 numeric success rate --</p> <p>23 A. No, I don't have a --</p> <p>24 Q. -- in conjunction with those</p>	<p style="text-align: right;">Page 238</p> <p>1 A. I took my total number of</p> <p>2 reoperations and my total number of cases and</p> <p>3 just divided it.</p> <p>4 Q. And what --</p> <p>5 A. So it's a rough number.</p> <p>6 Q. And what is the numerator and</p> <p>7 denominator for those?</p> <p>8 A. I don't recall, as I sit here</p> <p>9 right now. I would have to look at it.</p> <p>10 Q. And who did -- who did the</p> <p>11 review?</p> <p>12 A. Myself.</p> <p>13 Q. Is there any documentation</p> <p>14 regarding the review or your findings that</p> <p>15 you used to come up with those rates?</p> <p>16 A. I have an operative log that I</p> <p>17 keep.</p> <p>18 Q. Do you know if that's been</p> <p>19 produced to us in this litigation?</p> <p>20 A. No, I don't believe so.</p> <p>21 MR. FAES: We would ask that</p> <p>22 that would be produced if the doctor</p> <p>23 is going to offer any opinions about</p> <p>24 her reoperation rates at trial.</p>

26 (Pages 235 to 238)

Christina Pramudji, M.D.

Page 239	Page 241
<p>1 MR. GAGE: I'll consult with 2 her and let you know what our position 3 is on that. 4 BY MR. FAES: 5 Q. Did you do any kind of analysis 6 of patients that were lost to follow-up? 7 A. No, I did not. 8 Q. What time frame were you using 9 for your reoperation rates to come up with 10 your reoperation rate number for Prolift and 11 Prosima? 12 A. Well, I just -- just from 13 the -- when I started using the products 14 until I did the analysis, however many years 15 that was. I can't remember when I did that 16 analysis. 17 Q. But you can't state a specific 18 year that you started and stopped? 19 A. No, I can't remember right now. 20 Q. But it's fair to say it would 21 go back to when you were working in Dallas in 22 Dr. Anhalt's practice, correct? 23 A. Well, yeah. It wasn't in 24 Dallas. It was here in Houston. But, yes,</p>	<p>1 many reoperations did I do? And this is 2 just -- this isn't even -- this is just like 3 a mesh exposure, mesh explant-type 4 reoperation. It's not comprehensive. 5 Q. Okay. I think you've answered 6 my question on that. 7 I hate to do this to you, but 8 since there's no invoices yet on your 9 case-specific depositions that you're going 10 to be offering opinions on, I need to go 11 through and ask you if you have a rough 12 estimate of the number of hours you've spent 13 on each of your cases. Do you know 14 approximately how many hours you've spent on 15 the Sharon Carpenter case? 16 MR. GAGE: Let me just say, I 17 assume that by doing this that the 18 individual lawyers will not ask the 19 question and that you would agree as 20 liaison counsel that I can say "asked 21 and answered," we don't have to do it 22 during the individual cases? 23 MR. FAES: Well, they might ask 24 more specific questions, like break</p>
Page 240	Page 242
<p>1 back to 2005, when I started doing the 2 Prolift, until I did the analysis, because 3 there may have been some complications that 4 were treated after I stopped using the 5 products. But I can't remember when I did 6 that. 7 Q. And if a doctor [sic] needed a 8 reoperation and went to a different doctor 9 other than you, you wouldn't have that 10 information unless the patient shared it with 11 you, correct? 12 A. That's correct. 13 Q. So your reoperation rates that 14 you calculated would exclude any patients 15 that went to other doctors for reoperation 16 that you didn't know about, correct? 17 A. Yes. But kind of what I did in 18 reverse, which this is very rough, but I 19 included patients that came from other 20 doctors in my reoperation rate. So some 21 patients were not my original -- I was not 22 the original implantor. So it's kind of -- 23 it's a very rough analysis. There's just 24 sort of, okay, I did this many implants; how</p>	<p>1 down the amount or whatever, but, 2 yeah, you can certainly object. 3 MR. GAGE: Okay. 4 BY MR. FAES: 5 Q. Do you recall how many hours 6 you've spent on the Sharon Carpenter case? 7 A. I don't recall. 8 Q. Do you recall how many hours 9 you've spent on the Mary Jane Olson case? 10 A. I don't remember. 11 Q. You don't have any kind of 12 estimate, as you sit here today, or any 13 documentation regarding how many hours you've 14 spent on that case? 15 A. I would say maybe 30 to 16 50 hours on each case, let's say. That may 17 be high; that may be low. It depends. Some 18 of them are more complicated than others. 19 Q. So you estimate -- your best 20 estimate, as you sit here today, on all the 21 cases, case-specific cases that you are going 22 to offer opinions on in the next couple of 23 days, is that you spent approximately 30 to 24 50 hours on each of those cases?</p>

27 (Pages 239 to 242)

Christina Pramudji, M.D.

Page 243	Page 245
<p>1 A. Uh-huh. Yes.</p> <p>2 Q. And that rate at this point</p> <p>3 that you've charged for those cases is \$600</p> <p>4 an hour for review?</p> <p>5 A. Correct.</p> <p>6 Q. And your deposition testimony</p> <p>7 will be 700 an hour, correct?</p> <p>8 A. Correct.</p> <p>9 Q. And that's the same rate as if</p> <p>10 you get called for trial?</p> <p>11 A. Correct.</p> <p>12 (Deposition Exhibit 14 marked.)</p> <p>13 BY MR. FAES:</p> <p>14 Q. Doctor, I'm going to hand you</p> <p>15 what's been marked as Exhibit No. 14 to your</p> <p>16 deposition.</p> <p>17 (Witness Reviews Document.)</p> <p>18 BY MR. FAES:</p> <p>19 Q. Doctor, this is an e-mail from</p> <p>20 you to Robert Zipfel, Z-i-p-f-e-l, at Ethicon</p> <p>21 responding to a press release regarding the</p> <p>22 launch of the Prolift+M; is that correct?</p> <p>23 A. Correct.</p> <p>24 Q. I'm not going to ask you about</p>	<p>1 that are lighter weight and larger pore than</p> <p>2 the mesh used in the original Prolift device,</p> <p>3 correct?</p> <p>4 MR. GAGE: Object to form.</p> <p>5 A. I think -- you said the pores</p> <p>6 are lighter weight. I don't know if that's</p> <p>7 what you meant to say.</p> <p>8 BY MR. FAES:</p> <p>9 Q. That's not what I meant to say.</p> <p>10 A. Okay.</p> <p>11 Q. I'll re-ask the question. And</p> <p>12 you know that this Prolift+M device uses a</p> <p>13 mesh that has larger pores and is of a</p> <p>14 lighter weight than the mesh used in the</p> <p>15 original Prolift device, correct?</p> <p>16 A. I believe after the Monocryl is</p> <p>17 observed, then it becomes a lighter-weight</p> <p>18 mesh.</p> <p>19 Q. In fact, it becomes almost half</p> <p>20 the weight of the mesh used in the Prolift;</p> <p>21 isn't that correct?</p> <p>22 A. That sounds about right.</p> <p>23 Q. And this Prolift+M device, you</p> <p>24 would agree, did ultimately become your</p>
Page 244	Page 246
<p>1 this whole thing, but if you go down to the</p> <p>2 third paragraph, it says, "This</p> <p>3 lightweight" -- with regard to the Prolift+M,</p> <p>4 it says, "This lightweight polypropylene mesh</p> <p>5 is less dense and has larger pores than</p> <p>6 previous meshes, which could lead to</p> <p>7 decreases in reactive scar formation and a</p> <p>8 reduction in inflammatory response during</p> <p>9 healing. This mesh also has properties that</p> <p>10 help the surgeon place the mesh more easily</p> <p>11 because it resists wrinkling and folding, and</p> <p>12 it has increased longitudinal elasticity</p> <p>13 while maintaining lateral support to ensure</p> <p>14 pliability after surgery. The new design may</p> <p>15 improve vaginal wall compliance and allow for</p> <p>16 better tissue incorporation."</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. Is this your understanding of</p> <p>20 what Ethicon believed were the potential</p> <p>21 benefits of the Prolift+M device?</p> <p>22 A. Yes, that's my understanding.</p> <p>23 Q. And you know that this</p> <p>24 Prolift+M device uses a mesh that has pores</p>	<p>1 device of choice over the Prolift for the</p> <p>2 treatment of pelvic organ prolapse?</p> <p>3 A. Yes.</p> <p>4 Q. That's all the questions I have</p> <p>5 about that document.</p> <p>6 A. Okay.</p> <p>7 (Deposition Exhibit 15 marked.)</p> <p>8 BY MR. FAES:</p> <p>9 Q. Doctor, I'm going to hand you</p> <p>10 what's been marked as Exhibit No. 15 to your</p> <p>11 deposition.</p> <p>12 A. Okay.</p> <p>13 Q. And I just have a real quick</p> <p>14 question about this. This is a document</p> <p>15 dated February 27th, 2008, titled "Prosima</p> <p>16 Launch Plan." And if you turn to the second</p> <p>17 page under "Southern Region," you see that</p> <p>18 your name is listed as the third name on the</p> <p>19 first column. Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. Does this document indicate</p> <p>22 that you were one of the initial preceptors</p> <p>23 for the launch of the Prosima device?</p> <p>24 A. It looks like I was targeted</p>

28 (Pages 243 to 246)

Christina Pramudji, M.D.

Page 247	Page 249
<p>1 for that, but, honestly, I can't remember the 2 timeline on that. 3 Q. Do you remember if you were one 4 of the initial preceptors for the Proxima 5 device? 6 A. I don't remember. 7 Q. So you could've been or you 8 might not have been; you just don't know one 9 way or the other? 10 A. Yes, I can't remember. 11 Q. That's all the questions I have 12 for that document. 13 (Deposition Exhibit 16 marked.) 14 (Deposition Exhibit 17 marked.) 15 BY MR. FAES: 16 Q. I'm going to hand you what's 17 been marked as Exhibits 16 and 17. 18 Doctor, Exhibit No. 16 is an 19 e-mail dated January 13th, 2009, regarding a 20 urology meeting follow-up. Do you see that? 21 A. Yes. 22 BY MR. FAES: 23 Q. If you turn to the fourth page 24 where it discusses the "Blue Group," you see</p>	<p>1 prolapse? 2 A. Well, this was right after the 3 2008 FDA notification, so that may have been 4 where some of that sentiment came from. But 5 I don't recall specifically any conversations 6 at that conference. 7 Q. My question was actually a 8 little bit different than that. So I'm going 9 to re-ask it. 10 A. Okay. 11 Q. Did you believe, at this time 12 in 2009, that it was important to ease the 13 fears of patients with regard to the safety 14 of mesh devices for the treatment of pelvic 15 organ prolapse? 16 A. I'm sorry, can you repeat that 17 one more time? 18 Q. Did you believe, at this time 19 in 2009, that it was an important goal to 20 ease the fears of patients with regard to the 21 safety of mesh devices for the treatment of 22 pelvic organ prolapse? 23 A. I can't remember what I thought 24 at that time.</p>
Page 248	Page 250
<p>1 that you are listed, as the sixth name down, 2 as participating in this group. Do you see 3 that? 4 A. Yes. 5 Q. Do you remember participating 6 in this group in 2009? 7 A. Vaguely. 8 Q. If you look down under 9 "Recommendations to Group: Patient 10 Education," the fourth bullet point down, it 11 states, "Safety long-term communicate to 12 patients, this eases their fears." Do you 13 see that? 14 MR. GAGE: Object to form. 15 A. Yes, I see that. 16 BY MR. FAES: 17 Q. Did you -- was this a 18 recommendation that you remember the team 19 making to Ethicon? 20 A. I don't remember. 21 Q. Did you believe, at this time 22 in 2009, it was important to ease the fears 23 of patients with regard to the safety of mesh 24 devices for the treatment of pelvic organ</p>	<p>1 Q. You see the second bullet point 2 down, it says, "Google - have EWHU" -- which 3 you know stands for "Ethicon Women's Health & 4 Urology," correct? 5 A. Correct. 6 Q. -- "website precede litigation 7 websites." You see that? 8 A. Yes. 9 Q. So one of the recommendations 10 of the team was to pay Google to have 11 Ethicon's website appear before any 12 litigation websites on Google searches? 13 A. That's what it appears to be. 14 Q. Now, you stated that the 15 litigation environment changed in 2012 and 16 that's when you believed that pelvic organ 17 prolapse devices should not be considered for 18 first-line treatment, correct? 19 A. That's when it really seemed to 20 ramp up. 21 Q. But, at least according to this 22 document in 2009, fears about lawsuits were 23 of concern going back to 2009 -- 24 A. That's what it looks like --</p>

29 (Pages 247 to 250)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 251</p> <p>1 Q. -- is that correct?</p> <p>2 A. -- according to this.</p> <p>3 Q. Did -- do you recall at this</p> <p>4 meeting like -- do you recall if at this</p> <p>5 meeting you felt like Ethicon and physicians</p> <p>6 felt like you needed to do damage control to</p> <p>7 address the 2008 public health notification?</p> <p>8 A. I don't recall.</p> <p>9 Q. Would you agree that if the</p> <p>10 fear of being named in a lawsuit prevents</p> <p>11 someone from using a product that is unsafe,</p> <p>12 that that's a good thing?</p> <p>13 A. Can you repeat that for me,</p> <p>14 please.</p> <p>15 Q. Would you agree that if the</p> <p>16 fear of being named in lawsuits prevents</p> <p>17 someone from selling a product that is</p> <p>18 unsafe, that that's a good thing?</p> <p>19 A. No, I don't think that's a good</p> <p>20 thing.</p> <p>21 Q. Well, you'd agree that asbestos</p> <p>22 in this country is generally no longer being</p> <p>23 sold, right?</p> <p>24 A. I don't know anything about</p>	<p style="text-align: right;">Page 253</p> <p>1 asbestos fibers can cause lung cancer, but</p> <p>2 beyond that, I really don't have an opinion.</p> <p>3 Q. So if fear of being sued</p> <p>4 prevented a company from putting out an</p> <p>5 asbestos product that could be inhaled into</p> <p>6 the body and that was the only thing that</p> <p>7 kept that company from putting that product</p> <p>8 out, do you believe that would be a bad</p> <p>9 thing?</p> <p>10 A. I don't know. I don't have an</p> <p>11 opinion about that.</p> <p>12 Q. If you go to the last bullet</p> <p>13 point, "Recommendations to Group: Clinical</p> <p>14 Data," it says, "Do studies on ISD" -- which</p> <p>15 I assume is intrinsic sphincter deficiency --</p> <p>16 "smokers, obesity and safety." Do you see</p> <p>17 that?</p> <p>18 A. Yes.</p> <p>19 Q. So at this time in 2009, one of</p> <p>20 the recommendations to Ethicon, that this</p> <p>21 group that you participated in, was that</p> <p>22 Ethicon needed more data on safety.</p> <p>23 A. What it says here is they --</p> <p>24 the recommendation was to do studies on</p>
<p style="text-align: right;">Page 252</p> <p>1 asbestos.</p> <p>2 Q. You don't know anything about</p> <p>3 asbestos?</p> <p>4 A. No.</p> <p>5 Q. You don't know whether -- as a</p> <p>6 physician, whether or not asbestos causes</p> <p>7 cancer and is hazardous to human health?</p> <p>8 A. I do know that it causes</p> <p>9 mesothelioma, but I don't know about the</p> <p>10 asbestos product line or market or lawsuits</p> <p>11 or anything like that.</p> <p>12 Q. Would you agree that asbestos</p> <p>13 should never be used in a medical device?</p> <p>14 A. I don't know why it would be</p> <p>15 used in a medical device.</p> <p>16 Q. That's not my question. Would</p> <p>17 you agree that asbestos should never be used</p> <p>18 in a medical device?</p> <p>19 A. I don't know. I don't know</p> <p>20 enough about it.</p> <p>21 Q. You don't know whether or not</p> <p>22 it's harmful for asbestos to be placed in</p> <p>23 continuous contact with the human body?</p> <p>24 A. Well, I know that inhalation of</p>	<p style="text-align: right;">Page 254</p> <p>1 safety. I don't -- that's all I can say</p> <p>2 about it.</p> <p>3 Q. One of the other</p> <p>4 recommendations was that Ethicon get more</p> <p>5 data on how the mesh could be used in people</p> <p>6 who were obese or smoked.</p> <p>7 A. That's what it says here.</p> <p>8 Q. Does that indicate that at this</p> <p>9 time there wasn't sufficient data on how the</p> <p>10 mesh behaved in individuals who were obese or</p> <p>11 smoked?</p> <p>12 A. I don't know. I would have to</p> <p>13 look at what studies were available at that</p> <p>14 time in 2008.</p> <p>15 MR. FAES: William, I could go</p> <p>16 on, but I think I'm at about my</p> <p>17 two-hour limit.</p> <p>18 MR. GAGE: Okay. I guess I do</p> <p>19 my follow-up?</p> <p>20 MR. FAES: Yeah.</p> <p>21 MR. GAGE: Let me take just a</p> <p>22 little break.</p> <p>23 (Recess Taken From 10:41 a.m.</p> <p>24 To 10:53 a.m.)</p>

30 (Pages 251 to 254)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 255</p> <p>1 EXAMINATION</p> <p>2 BY MR. GAGE:</p> <p>3 Q. Dr. Pramudji, my name is</p> <p>4 William Gage, and I've got just a couple of</p> <p>5 questions for you. You were asked, I believe</p> <p>6 yesterday, some questions about the Prosima</p> <p>7 IFU. Do you recall that?</p> <p>8 A. Yes.</p> <p>9 Q. And in particular, some of the</p> <p>10 questions related to whether the IFU -- the</p> <p>11 Prosima IFU referenced anything about</p> <p>12 stage IV pelvic organ prolapse. Do you</p> <p>13 recall those questions?</p> <p>14 A. Yes.</p> <p>15 Q. Do you recall generally what</p> <p>16 the question that was posed to you was?</p> <p>17 A. I think it was the indications</p> <p>18 for the Prosima for what stage it's</p> <p>19 indicated.</p> <p>20 Q. And were you asked whether the</p> <p>21 Prosima IFU made any references with regard</p> <p>22 to stage IV?</p> <p>23 A. I believe so.</p> <p>24 Q. And do you remember what your</p>	<p style="text-align: right;">Page 257</p> <p>1 asked about it had forgotten?</p> <p>2 A. Yes, I had forgotten about</p> <p>3 that.</p> <p>4 Q. Doctor, you were asked a number</p> <p>5 of questions yesterday and perhaps some today</p> <p>6 about certain opinions that you have where</p> <p>7 you disagree with the FDA. Do you recall</p> <p>8 those questions?</p> <p>9 A. Yes.</p> <p>10 Q. Are you alone among pelvic</p> <p>11 floor surgeons in disagreeing with the FDA on</p> <p>12 certain issues related to pelvic organ</p> <p>13 prolapse mesh?</p> <p>14 A. No. As a matter of fact, there</p> <p>15 is a network of dozens of pelvic surgeons who</p> <p>16 have even issued statements disagreeing with</p> <p>17 the FDA.</p> <p>18 Q. And at a high level, what are</p> <p>19 those disagreements with regard to pelvic</p> <p>20 organ prolapse mesh?</p> <p>21 A. The disagreements are that --</p> <p>22 the statement that the complications are not</p> <p>23 rare, because the literature and the personal</p> <p>24 use indicates that the complications are</p>
<p style="text-align: right;">Page 256</p> <p>1 answer was?</p> <p>2 A. I did not think it made a</p> <p>3 reference to that.</p> <p>4 Q. Okay. I'm handing you the</p> <p>5 Prosima IFU that today has been marked as</p> <p>6 Exhibit 11, and I'm showing you the warnings</p> <p>7 and precautions section of the IFU. Do you</p> <p>8 see that?</p> <p>9 A. Yes.</p> <p>10 Q. And the second bullet under</p> <p>11 "Warnings and Precautions" says, "Use of the</p> <p>12 Gynecare Prosima System has not been fully</p> <p>13 evaluated in patients with Stage IV pelvic</p> <p>14 organ prolapse. Therefore its use in these</p> <p>15 patients is not recommended."</p> <p>16 Did I read that correctly?</p> <p>17 A. Yes.</p> <p>18 Q. What is the significance, if</p> <p>19 any, of that statement to your answers</p> <p>20 yesterday about stage IV and the Prosima IFU?</p> <p>21 A. Yes. So the IFU indicates that</p> <p>22 it is not recommended for stage IV prolapse.</p> <p>23 Q. And is that something you read</p> <p>24 that had just -- yesterday when you were</p>	<p style="text-align: right;">Page 258</p> <p>1 rare. And also that the benefits of mesh are</p> <p>2 in question; whereas studies, particularly</p> <p>3 for a cystocele repair, indicate that there</p> <p>4 is a definite benefit in efficacy using mesh</p> <p>5 implants.</p> <p>6 Q. You have been asked some</p> <p>7 questions yesterday and today about whether</p> <p>8 the mesh in Prosima, Prolift and Gynemesh PS</p> <p>9 was cut with a machine or cut with a laser.</p> <p>10 Do you recall those questions?</p> <p>11 A. Yes.</p> <p>12 Q. What is the clinical</p> <p>13 significance, if any, as to whether the mesh</p> <p>14 in those three devices is cut by a machine</p> <p>15 with a blade or cut by a laser?</p> <p>16 A. There's really no clinical</p> <p>17 impact one way or another as far as efficacy</p> <p>18 or complications. And particularly, as I</p> <p>19 mentioned earlier, most surgeons are going to</p> <p>20 trim the edges of the mesh to some degree or</p> <p>21 another, usually quite extensively, and</p> <p>22 therefore the edges effectively all become</p> <p>23 scissor cut when they're implanted.</p> <p>24 Q. Doctor, how long have you been</p>

31 (Pages 255 to 258)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 259</p> <p>1 working with Ethicon on the pelvic organ 2 prolapse mesh litigation? Do you recall when 3 you were first retained? 4 A. I think it was three years ago, 5 if I remember correctly. 6 Q. Is it fair to say that you've 7 reviewed a lot of materials going back to 8 that date? 9 A. Yes. 10 Q. And some of that would include 11 company documents? 12 A. That's correct. 13 Q. And would you have also 14 reviewed patient medical records? 15 A. Yes. 16 Q. You testified earlier that you 17 were unaware that the indications section of 18 the Gynemesh PS IFU had been changed 19 recently. Do you recall that? 20 A. Yes. 21 Q. Is it possible that that was a 22 fact that you knew from your prior and 23 earlier work on the pelvic organ prolapse 24 litigation, but it is something that when you</p>	<p style="text-align: right;">Page 261</p> <p>1 grade IV prolapse. 2 A. That's correct. 3 Q. You said that there are other 4 pelvic floor surgeons who disagree with the 5 FDA and that there are organizations of those 6 physicians. What are those organizations? 7 A. I think it's called the Pelvic 8 Floor Mesh Network. 9 Q. Are you a member of that 10 organization? 11 A. I signed on to the 12 communication. It's not -- I don't know that 13 it's an organization per se, or if it was 14 just a consortium of surgeons that were all 15 of like mind as far as pelvic surgery. 16 Q. Do you know how many surgeons 17 belong to that organization? 18 A. Seems like there were dozens on 19 the e-mails. But I don't know an exact 20 number. 21 Q. You don't know a number -- 22 A. No. 23 Q. -- as you sit here today? So 24 it's possible that this is an organization of</p>
<p style="text-align: right;">Page 260</p> <p>1 were asked that question you had forgotten? 2 A. Yes, that's entirely possible, 3 with all the voluminous information I've 4 tried to absorb. 5 MR. GAGE: That's all I have. 6 MR. FAES: Just a couple of 7 questions, Doctor. 8 FURTHER EXAMINATION 9 BY MR. FAES: 10 Q. With regard to the Prosima IFU, 11 you'd agree that in the indications-for-use 12 section, there's nothing in the IFU that says 13 that the Prosima should only be used for 14 grades II and III prolapse, correct? 15 A. In that section, that is 16 correct. 17 Q. You'd agree that there's 18 nothing in that section that informs 19 physicians that it shouldn't be used for a 20 grade IV prolapse, correct? 21 A. That's correct. 22 Q. In fact, there's no 23 contraindication in this section informing 24 physicians that it's not indicated for</p>	<p style="text-align: right;">Page 262</p> <p>1 outlier physicians who disagree with the FDA 2 since you don't know the number of physicians 3 that belong to this group? 4 A. No, these were mainstream 5 surgeons, prolific users that had a lot of 6 experience and had -- 7 Q. How do you know that there're 8 mainstream users who are other members of 9 this organization? 10 A. Well, in particular I remember 11 Dr. Lucente, Dr. Supulveda. That's all I can 12 remember off the top of my head. But it was 13 people that I was familiar with that -- 14 professors, people that had a lot of 15 experience with pelvic mesh that had seen how 16 it actually behaved in patients. 17 Q. You know that Dr. Supulveda is 18 an expert in mesh litigation, correct? 19 A. Yes. 20 Q. You know that Dr. Lucente is an 21 expert in mesh litigation, correct? 22 A. I didn't know about that. 23 Q. You know that Dr. Lucente has 24 received over a million dollars from Ethicon</p>

Christina Pramudji, M.D.

Page 263	Page 265
<p>1 for his consulting work related to mesh, 2 correct? 3 A. I don't know about that. 4 MR. GAGE: Object to form. 5 BY MR. FAES: 6 Q. If those -- if that's true, 7 that Dr. Lucente has received over a million 8 dollars, wouldn't that present a conflict for 9 him when he had a financial incentive to 10 support the continued use of mesh? 11 A. No. I don't see that as a 12 major conflict. 13 Q. You don't think a person who's 14 made over a million dollars off of mesh 15 consulting would have an incentive to have 16 the use of mesh continue? 17 A. You know, I think it's fair for 18 physicians to be compensated for their time. 19 You want people that use it a lot to be your 20 consultant and to train other people and they 21 need to be compensated. So I don't know -- I 22 don't see how you can avoid that issue. I 23 don't -- and I can't speak to his motivation. 24 MR. FAES: I'm going to object</p>	<p>1 A. No, I would -- I would say -- I 2 would say that's not rare. 3 Q. Would you say an event that -- 4 an adverse event that occurs in one out of 5 five patients is common? 6 A. I wouldn't say common. 7 Q. But you would agree that it's 8 not rare? 9 A. Yeah, I would not call that 10 rare. 11 Q. You state that you know of -- 12 you don't believe there's a clinical impact 13 between the use of laser cut or mechanically 14 cut mesh. Are you aware of any clinical 15 study that specifically looked at the safety 16 as a primary end point between laser cut and 17 mechanically cut surgical mesh? 18 A. Not that I can think of right 19 now. 20 Q. Do you believe that you at one 21 point knew that the indications for use for 22 the Gynemesh PS had changed in 2013 and just 23 forgot? 24 A. Yes. I just forgot about that.</p>
Page 264	Page 266
<p>1 and move to strike as nonresponsive. 2 I'm going to re-ask it because I don't 3 think you've answered my question. 4 A. Sorry. 5 BY MR. FAES: 6 Q. Do you think a person who's 7 made over a million dollars off of mesh 8 consulting would have an incentive to see the 9 use of mesh continue? 10 A. I don't know. 11 Q. Are there any other 12 organizations you're aware of that disagree 13 with the FDA's stance on pelvic mesh other 14 than the Pelvic Floor Mesh Network? 15 A. Not that I can think of right 16 as I sit here. 17 Q. You specifically said that one 18 of the things that the FDA said that this 19 organization disagrees with is that 20 complications associated with pelvic organ 21 prolapse mesh are not rare; is that correct? 22 A. That's correct. 23 Q. Do you consider an event that 24 occurs in one out of five people to be rare?</p>	<p>1 Q. Do you feel like that's an 2 important fact that you should know in 3 rendering an opinion about whether or not the 4 Gynemesh PS, Prolift and Prolene Soft is 5 defective? 6 A. No, I don't think it matters 7 one way or another. 8 MR. FAES: That's all the 9 questions I have. 10 MR. GAGE: I don't have any 11 follow-up. 12 (Deposition Concluded At 13 11:06 a.m.) 14 --o0o-- 15 16 17 18 19 20 21 22 23 24</p>

33 (Pages 263 to 266)

Christina Pramudji, M.D.

Page 267	Page 269
<p>1 CERTIFICATE</p> <p>2 I, MICHEAL A. JOHNSON, Registered</p> <p>3 Diplomat Reporter, Certified Realtime</p> <p>4 Reporter, Certified Court Reporter and Notary</p> <p>5 Public, do hereby certify that prior to the</p> <p>6 commencement of the examination, CHRISTINA</p> <p>7 PRAMUDJI, M.D. was duly sworn by me to</p> <p>8 testify to the truth, the whole truth and</p> <p>9 nothing but the truth.</p> <p>10 I DO FURTHER CERTIFY that the</p> <p>11 foregoing is a verbatim transcript of the</p> <p>12 testimony as taken stenographically by and</p> <p>13 before me at the time, place and on the date</p> <p>14 hereinbefore set forth, to the best of my</p> <p>15 ability.</p> <p>16 I DO FURTHER CERTIFY that pursuant</p> <p>17 to FRCP Rule 30, signature of the witness was</p> <p>18 not requested by the witness or other party</p> <p>19 before the conclusion of the deposition.</p> <p>20 I DO FURTHER CERTIFY that I am</p> <p>21 neither a relative nor employee nor attorney</p> <p>22 nor counsel of any of the parties to this</p> <p>23 action, and that I am neither a relative nor</p> <p>24 employee of such attorney or counsel, and</p> <p>that I am not financially interested in the</p> <p>action.</p> <p>MICHEAL A. JOHNSON, RDR, CRR NCRA Registered Diplomat Reporter NCRA Certified Realtime Reporter Certified Court Reporter</p> <p>Notary Public in and for the State of Texas My Commission Expires: 8/8/2016</p> <p>Dated: March 24, 2016</p>	<p>1 ERRATA</p> <p>2 PAGE LINE CHANGE</p> <p>3</p> <p>4 REASON: _____</p> <p>5</p> <p>6 REASON: _____</p> <p>7</p> <p>8 REASON: _____</p> <p>9</p> <p>10 REASON: _____</p> <p>11</p> <p>12 REASON: _____</p> <p>13</p> <p>14 REASON: _____</p> <p>15</p> <p>16 REASON: _____</p> <p>17</p> <p>18 REASON: _____</p> <p>19</p> <p>20 REASON: _____</p> <p>21</p> <p>22 REASON: _____</p> <p>23</p> <p>24 REASON: _____</p>
Page 268	Page 270
<p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition over</p> <p>4 carefully and make any necessary corrections.</p> <p>5 You should state the reason in the</p> <p>6 appropriate space on the errata sheet for any</p> <p>7 corrections that are made.</p> <p>8 After doing so, please sign the</p> <p>9 errata sheet and date it.</p> <p>10 You are signing same subject to</p> <p>11 the changes you have noted on the errata</p> <p>12 sheet, which will be attached to your</p> <p>13 deposition.</p> <p>14 It is imperative that you return</p> <p>15 the original errata sheet to the deposing</p> <p>16 attorney within thirty (30) days of receipt</p> <p>17 of the deposition transcript by you. If you</p> <p>18 fail to do so, the deposition transcript may</p> <p>19 be deemed to be accurate and may be used in</p> <p>20 court.</p>	<p>1 ACKNOWLEDGMENT OF DEPONENT</p> <p>2</p> <p>3</p> <p>4 I, CHRISTINA PRAMUDJI, M.D., do</p> <p>5 hereby certify that I have read the foregoing</p> <p>6 pages and that the same is a correct</p> <p>7 transcription of the answers given by me to</p> <p>8 the questions therein propounded, except for</p> <p>9 the corrections or changes in form or</p> <p>10 substance, if any, noted in the attached</p> <p>11 Errata Sheet.</p> <p>12</p> <p>13 CHRISTINA PRAMUDJI, M.D. DATE</p> <p>14</p> <p>15 Subscribed and sworn to before me this</p> <p>16 _____ day of _____, 20 ____.</p> <p>17 My commission expires: _____</p> <p>18</p> <p>19 _____</p> <p>20 Notary Public</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

34 (Pages 267 to 270)

Christina Pramudji, M.D.

Page 271		
1	LAWYER'S NOTES	
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abdominal 145:18 161:18 173:8 abdominally 219:1 ability 267:9 able 174:16 175:13 190:16 192:6 absolutely 154:22 236:7 absorb 260:4 access 216:3,10,22 accompanied 197:20 accurate 208:14 268:19 acknowledgment 143:13 270:1 acog 206:16 action 267:14,15 actions 209:13 acute 160:5 161:17 add 157:23 164:11 added 156:22 162:16 163:5 167:8,15 218:3 addition 144:8 address 251:7 adequate 150:5 151:6,20 admitted 149:23 admitting 151:11 adopted 192:23 advantages 189:8 222:9 adverse 155:11,16 156:3 157:18 158:10,14,24 161:22 162:15 164:12 166:19 167:2,8,15,21 168:9 198:10 216:19 218:3 265:4 advertising 208:8 afaes 141:3 affect 169:7 173:16	affirmative 152:4 ago 146:1,4 147:1 170:13 259:4 agree 147:23 150:4 151:19 157:11 158:6 177:23 178:4,8,13 180:5 180:22 181:3 183:9 197:4,17 202:22 203:10 205:24 206:9 207:9,12,18 208:4 208:16,20 209:11 209:19 210:1,10 211:15 212:16 213:2,14 215:7,15 216:4 223:24 224:9,12,14,15,19 224:23 225:6,9 226:1,6 227:3,7 227:23 228:5,15 228:19 229:13,21 230:14 232:23 241:19 245:24 251:9,15,21 252:12,17 260:11 260:17 265:7 agreed 171:16,18 198:18 208:2 218:23 219:10 al 144:14 allen 141:8 allow 244:15 allowed 173:5 215:2 allowing 172:18 218:22 219:8 alternative 209:21 210:3,11 222:3 america 167:7,14 amid 191:19,22 192:9,17 193:8,15 193:20 amount 182:24 183:10 201:16 242:1	amsden 139:11 141:10 analysis 186:24 187:5,16,20 188:1 239:5,14,16 240:2 240:23 andrew 141:2 anhalts 239:22 answer 148:12 149:6,11,14 153:6 153:9,15 157:3,4 157:7,9,10 158:2 174:21 177:4 179:14 193:2 194:15 196:22 199:22 204:13 206:4,8 210:7 222:7 223:18 225:4,14 230:12 230:13 235:3,6 256:1 answered 146:22 156:21 197:2 241:5,21 264:3 answers 256:19 270:5 anticipated 146:15 anymore 171:19 210:6 anyway 182:3 191:1 221:3,14 222:6 232:19 apical 169:21 apparently 170:1 appear 250:11 appearances 143:4 appears 250:13 applications 188:1 applies 186:21 192:17 196:17 apply 176:4 approach 169:24 approaches 209:21 209:21 210:3,12 appropriate 150:6 151:7,20 207:8	228:22 229:1 268:6 approximately 146:23 241:14 242:23 area 146:19 161:19 184:6,13 224:7 arrived 237:23 article 202:9 articles 180:1,6,8 182:8,10,14 196:15 asbestos 251:21 252:1,3,6,10,12 252:17,22 253:1,5 aside 178:16 asked 174:22 176:11 184:10 188:18 209:22 210:15 223:3 241:20 255:5,20 257:1,4 258:6 260:1 asking 206:20 224:5 assess 180:23 assessing 233:24 associated 264:20 assume 170:22 172:12 241:17 253:15 assuming 172:6,11 202:23 assumption 194:22 attached 268:12 270:7 attachment 144:15 attention 220:17 attorney 208:7 267:13,14 268:16 attorneys 168:21 augmentation 153:4,5,12,19,23 aug 206:17 author 200:7 available 179:17	180:9 207:8 210:6 210:9 254:13 avenue 141:3,13 avoid 263:22 aware 149:21 150:1 151:10 165:14,20 167:21 170:3,6,18 172:1 177:21 201:5 204:18 213:24 214:17 230:20 231:2 264:12 265:14
				B
				back 145:7,14 147:10,20 150:10 150:12,24 164:20 172:19 179:6 191:6 226:15 237:13 239:21 240:1 250:23 259:7 backtrack 217:20 bad 174:23 176:11 209:22 253:8 banks 138:18 barbara 138:8 bard 230:10 barker 139:1 based 174:17,17 176:7,7 178:14 184:23,24 185:2 195:5 200:23 208:23,24 209:2,7 209:8 211:5,14 basis 186:13 bearing 209:17 beginning 140:8 150:15 163:6 164:2,9 behaved 229:4 254:10 262:16 behaves 189:12 behavior 189:2 believe 149:2 154:18,19 164:15

164:24 167:6,13 169:11,13,17 171:12 181:16,17 185:20 189:15 190:6,11 192:15 193:23 196:14 199:5 202:4,9 203:18,19,23,24 204:23 205:11 207:22 211:1,12 214:23 220:13 222:1 228:21 231:6,7,12 233:8 233:13,15 234:11 235:13 236:4 238:20 245:16 248:21 249:11,18 253:8 255:5,23 265:12,20 believed 164:17 165:2 194:6 201:16 244:20 250:16 belong 261:17 262:3 beneficial 209:5 benefit 153:12,18 153:22 154:11 258:4 benefits 244:21 258:1 best 182:15 242:19 267:8 better 176:12 203:16,16 223:22 224:6 229:15,23 230:12,16 244:16 beyond 185:19 253:2 bias 201:9,13,14 206:3,5,7,10,14 big 179:11 223:6 biological 154:4 biomedical 186:15 186:16,17,20 bit 174:24 176:12	182:20 196:19 217:21 235:3 249:8 bladder 161:12 blade 258:15 bleeding 159:4 blue 247:24 blynn 138:23 body 148:21 160:17 162:7 183:3,6,6,7 183:11 189:8 190:22 191:17 252:23 253:6 boggs 139:5 bowel 161:12 box 216:2 219:23 220:1 break 145:8 190:24 191:7,10 226:16 241:24 254:22 breaking 187:8,10 brenda 138:11 bridges 139:7 bridging 169:21 broke 145:11 bullet 248:10 250:1 253:12 256:10 butler 142:2 butlersnow 142:3 <hr/> C <hr/> c 141:1,6 142:1 calculated 237:2,11 240:14 call 146:12 265:9 called 209:9 230:9 243:10 261:7 callout 219:24 cancer 252:7 253:1 cant 149:15 151:8 155:20 157:10 158:2 180:23 181:6 187:9 204:24 214:3,9 215:8 220:20 222:7 237:11	239:15,17,19 240:5 247:1,10 249:23 263:23 career 145:22 careful 158:17 carefully 268:4 carey 139:8 199:6,7 199:10 200:21 201:7 205:18 careys 201:17 carol 139:23 carpenter 138:12 141:20 241:15 242:6 cartmell 141:2 case 138:7,8,10,11 138:13,14,16,17 138:19,20,22,23 139:1,3,4,6,7,9,10 139:12,13,15,16 139:18,19,21,22 139:24 146:1 154:21 169:18 173:14 180:14 181:1,6 185:24 201:24 236:11 237:7 241:15 242:6,9,14,16 cases 138:6 147:6 203:24 238:2 241:13,22 242:21 242:21,24 243:3 casespecific 241:9 242:21 cathy 139:10 cause 204:2,2 212:22 213:23 217:5,14 224:10 224:13,16,20,24 225:7,10,17,21 233:19 234:10 235:13 236:3 253:1 causes 224:21 252:6,8 causing 213:12	cells 190:15 cerda 141:6,7 certain 148:21 152:11,11 177:16 257:6,12 certainly 175:11 242:2 certainty 231:22 certificate 143:11 267:1 certified 140:11 267:2,3,19,19 certify 267:3,6,10 267:12 270:4 change 165:15 166:12 170:4,6 173:20,22 174:11 174:12 180:14,19 181:5 208:4 218:24 269:2 changed 170:13,21 170:24 172:10,16 218:14 219:19 220:3,19 250:15 259:18 265:22 changes 268:11 270:6 charged 243:3 charlene 139:20 charleston 138:2 chaves 144:14 choice 246:1 chosen 163:18,24 christina 138:9 140:5 143:1,6 144:1,7 145:2 267:4 270:4,12 chronic 160:5 161:17 cite 179:23 182:8 182:10 204:24 cited 202:9 city 140:7 141:4 claim 149:24 150:19,20 claims 148:6,15,18	149:3,11 211:5,11 211:13,14 class 209:15 classification 191:19 clear 204:4 clinical 148:18 150:3,21 152:6 180:12 195:6 196:18 200:12 203:12,15 204:18 229:13,21 230:15 232:18 234:5 253:13 258:12,16 265:12,14 clinically 190:4 203:11 227:23 228:6 closely 165:18 172:17 coffee 158:17 cole 139:8 collagen 192:7 colony 142:3 column 246:19 com 140:22 141:3,7 141:12,18 142:3 come 146:12 149:8 164:6 192:6 238:15 239:9 comfort 229:15,23 230:16 comfortable 174:1 175:13 176:3 181:12 commencement 267:4 comment 212:14 comments 144:16 commission 267:21 270:17 committee 206:15 207:1,5 common 265:5,6 communicate 168:17 169:4
--	---	---	--	--

248:11 communication 261:12 company 168:17 169:4 221:3,13 222:5 223:3,5 253:4,7 259:11 companys 220:24 221:10,24 222:14 comparing 232:11 compensated 263:18,21 complete 171:11 completion 213:4 compliance 244:15 compliant 226:4 227:21 complicated 242:18 complication 217:2 217:4,11,13 237:5 complications 155:3 213:6,18 214:21 224:2 234:11 236:4,20 237:8 240:3 257:22,24 258:18 264:20 comprehensive 180:8 241:4 conceive 175:11 concept 211:21 212:5,17 213:3 concern 250:23 concerned 234:8 235:9,20,24 concluded 266:12 conclusion 267:11 condition 173:4 conference 249:6 confident 185:1 configured 186:6 conflict 263:8,12 conjecture 187:14 conjunction 236:24 connection 211:22 212:6	consensus 220:23 221:9 222:11,13 consider 173:13 227:16,19 264:23 considered 205:9 227:8,12 250:17 considering 152:21 considers 168:20 consortium 261:14 consult 239:1 consultant 263:20 consultants 194:6 230:21 consulting 186:13 263:1,15 264:8 contact 252:23 contain 151:14 166:4,18 167:2 contained 166:19 167:3 contains 219:24 continue 173:21 175:12 263:16 264:9 continued 263:10 continuous 252:23 contract 198:23 contracting 199:2 contraction 161:6,9 197:21 198:1,3,4 198:7,8,14 202:5 203:20 204:1,22 contracts 198:19 contracture 223:12 223:16 224:1,7,10 224:13,16,20,24 225:7,10,17,21 contraindication 260:23 contrary 151:12 178:11 control 251:6 conversations 249:5 copy 178:18,23 179:8 182:3	206:20 corporations 221:19 correct 146:20 147:18,19 148:14 149:19 152:10 158:5 162:6 165:12,15,16,24 166:1 171:11,12 171:19 178:3 181:8 183:21 184:1,15,18 186:14 188:19 192:10,11,14 194:11 202:6,7 208:15,22 211:17 211:18 212:13 213:6 214:12,13 216:3,11,23 220:14 225:18,19 226:22 227:6,22 230:19 232:3 233:21,22 237:18 237:22 239:22 240:11,12,16 243:5,7,8,11,22 243:23 245:3,15 245:21 250:4,5,18 251:1 259:12 260:14,16,20,21 261:2 262:18,21 263:2 264:21,22 270:5 corrections 268:4,7 270:6 correctly 191:22 256:16 259:5 correspondence 201:23 cosson 205:3,9,12 205:16,20 206:1,9 cough 213:20 couldnt 212:14 couldve 163:18 247:7 counsel 141:5,10	141:15,20 142:5 241:20 267:13,14 country 211:2 251:22 couple 146:5,24 242:22 255:4 260:6 course 201:13 court 138:1 150:9 155:22 157:6,14 179:7 267:3,19 268:20 created 208:9 creating 197:18 crr 267:18 current 207:13,17 207:20 210:19 currently 178:12 cut 223:16 231:5,6 231:8,11,13,15,24 232:1,7,7,11,12 232:20,21,24 233:3,10 234:10 234:17,18,22 235:10,21 236:1 258:9,9,14,15,23 265:13,14,16,17 cutting 231:18,23 233:16 cystocele 258:3 <hr/> D <hr/> d 138:9 140:6 143:1 143:6 144:1 145:2 267:4 270:4,12 dallas 141:9 239:21 239:24 damage 160:11 251:6 daphne 139:1 data 148:8,17,22,22 149:4,13,24 150:19 180:13,23 181:5 182:15,16 201:18 204:19 205:2 222:21	253:14,22 254:5,9 date 140:9 259:8 267:8 268:9 270:12 dated 163:8 246:15 247:19 267:22 dave 144:16 day 164:3 270:16 days 242:23 268:16 de 141:6,7 dear 218:1 decide 176:18 decides 172:2 deciding 175:23 176:16 177:2 decision 177:15 decreases 244:7 deemed 169:2 268:19 defect 211:5,7 defective 266:5 defendants 142:5 deficiency 253:15 definite 258:4 definitely 167:21 189:10 definition 187:9 deform 190:2,8,11 190:11 deformed 196:22 197:7 deforming 196:20 deforms 196:13 degree 177:16 186:21 206:6 208:18 231:22 258:20 degrees 230:23 dehiscence 160:8 deliberately 182:10 182:13 delicate 233:20 denominator 238:7 dense 244:5 depending 148:1 depends 148:10,13
---	--	---	---	--

148:14,20,23 149:15 151:3 153:2 168:19 169:6,7 181:2 221:17,21 222:8 242:17 depo 178:19 deponent 143:13 270:1 deposing 268:15 deposition 138:8 140:5 144:1 151:11 155:24 162:19,23 179:19 181:22 182:2 210:17 243:6,12 243:16 246:7,11 247:13,14 266:12 267:11 268:3,13 268:17,18 depositions 241:9 deps 140:22 description 144:4 design 183:23 184:3,16,19,23 185:2,6,14,15,19 186:2,4,12,23 187:4,11 244:14 designed 186:8 197:23 designing 223:22 desirable 203:22 detail 172:4,23 180:4 details 171:21,23 222:8 determine 168:4,7 developed 192:13 193:21 228:16 229:7 development 184:9 186:9 device 148:7,16 149:13 153:7,10 158:14 159:3 163:11 164:2	165:10 168:10,15 168:17,18 169:1,4 169:5 170:13,24 171:10 172:14 174:7,16 175:3,4 175:8,9,23,24 176:16,17,19,20 177:1,3,15,17 182:22 183:23 184:3 186:12 188:6,12,14,22 197:5 199:4,11 200:2 201:9 204:3 205:22 209:15 211:16 212:5 214:1,2,11,16 216:8,10,20,21 219:19,24 220:18 221:1,3,10,12,14 222:2,6,12,14,16 222:17 223:5 244:21,24 245:2 245:12,15,23 246:1,23 247:5 252:13,15,18 devices 150:7 151:14 159:5,9,13 159:17,22 160:2 163:12 171:18 172:2,9,16,18 184:7,9,11 185:19 185:20 187:22 196:2,9 210:20 220:24 248:24 249:14,21 250:17 258:14 didnt 165:5 170:9 170:10 179:10 180:13 182:13 188:18 204:14 230:21 240:16 262:22 die 176:6 difference 232:6,18 different 145:15 182:7 184:11,15	213:1 229:20 235:4 240:8 249:8 differently 174:24 difficult 149:6 dimock 139:23 diplomate 140:10 267:2,18 directions 189:17 190:20 191:15 194:9,17 directors 228:21 disadvantages 189:9 disagree 181:10 194:10,19,20 207:9 209:1 224:11 225:16,23 228:22 229:2 232:14 234:2,4 235:16 257:7 261:4 262:1 264:12 disagreed 208:13 disagreeing 257:11 257:16 disagreements 257:19,21 disagrees 264:19 discomfort 225:10 discusses 247:24 discussing 145:12 discussion 179:1 dispute 198:2,3,6 district 138:1,1,5 divided 238:3 division 138:2 doctor 145:11 147:21 154:17 158:23 178:17 179:3 181:24 182:20 183:21 184:1 185:22 191:6 213:15 218:1 236:9 238:22 240:7,8 243:14,19 246:9	247:18 257:4 258:24 260:7 doctors 155:2 166:17,24 197:12 211:20 212:4,12 217:7,16 222:17 223:2,8 234:7,12 235:8 240:15,20 document 138:5 169:19 243:17 246:5,14,21 247:12 250:22 documentation 238:13 242:13 documents 201:23 259:11 doesnt 154:9 157:23 183:14 189:23 194:12 215:22 234:22 doing 172:3 234:15 240:1 241:17 268:8 dollars 262:24 263:8,14 264:7 donna 139:11 dont 146:3 147:2 149:5,8 150:10 156:18 158:18 162:8,13,18 163:15 164:13 165:4 167:17 171:3,5,20,22 172:4,22 173:10 173:15 176:5,6,18 177:4,5,6,11,14 179:16 183:22 184:2 187:1,8 188:19 189:20 190:14,18 191:13 192:22 193:10,18 193:23 194:3 196:18 197:15 199:8,12,13,15 200:4,16 201:19 202:1,4,19,21	205:19,23 206:19 206:19,22 210:24 211:24 212:8,11 212:22 215:6,20 217:18 218:6,10 219:3,6,13,20 220:10,12,15 223:1,6,8,23 224:8,21 227:18 228:19 229:11 232:17 233:8,13 233:15 236:23 237:2 238:8,20 241:21 242:7,10 242:11 245:6 247:6,8 248:20 249:5 251:8,19,24 252:2,5,9,14,19 252:19,21 253:2 253:10,10 254:1 254:12 261:12,19 261:21 262:2 263:3,11,13,21,22 263:23 264:2,10 265:12 266:6,10 doubt 180:19 dozens 257:15 261:18 dr 145:7 192:17 199:5,7,10 200:21 201:7,17 205:3,9 205:12,16,18,20 206:1,9 226:15 239:22 255:3 262:11,11,17,20 262:23 263:7 drawn 220:17 drive 141:19 due 229:24 230:17 duly 145:3 267:4 duration 183:2 durham 138:21 <hr/> E <hr/> e 141:1,1 142:1,1 earlier 258:19
--	--	---	---	---

259:16,23 early 193:15 ease 248:22 249:12 249:20 eases 248:12 easily 244:10 edge 232:20 233:9 233:16,18 edges 232:19 233:2 233:5 234:9,17 235:9,11 258:20 258:22 education 214:11 214:15,19 215:4,9 215:17 216:7 248:10 educations 216:18 edwards 141:6 edwardsdelacerda 141:7 effect 183:1 232:1 effective 205:6 209:4 222:3 effectively 258:22 effects 148:18 187:16,20 188:1 efficacy 174:11 258:4,17 eight 146:3 either 172:5 219:24 234:20 elasticity 244:12 elizabeth 138:23 email 144:10,14 178:21 243:19 247:19 emails 261:19 employee 267:13 267:14 ended 212:18 213:4 endings 204:7 ends 232:20 engineer 186:15,16 186:18 engineering 186:20 engineers 193:7,14	194:6 223:21 233:24 ensure 215:8,20 244:13 ensured 216:9,20 ensures 216:2 ensuring 215:16 entirely 260:2 environment 207:13,17,21 208:9,21 209:10 210:20 250:15 erosion 155:6,13 157:19 158:11 212:22,23 225:7 225:18,22 233:19 234:11 237:5 erosions 212:20 237:8 errata 143:12 268:6,9,11,15 269:1 270:7 esquire 141:2,7,12 141:17 142:2 essman 138:6 estimate 241:12 242:12,19,20 et 144:14 ethicon 138:3 144:12 147:21,22 148:6,8,15 149:3 149:11,13,23 151:10 152:2 156:7,7 157:17 163:7,11,18,24 164:11,16,16,24 165:1 166:2,6,16 166:24 171:9,17 171:18 172:1 173:3 193:4,7,14 193:23 194:5 197:12 200:7 201:16,23 211:19 212:3 215:2,8,16 216:2,5,14,16 217:2,6,10,15,24	218:12 219:9,16 219:22 224:5 225:21 228:16 229:7 230:20 232:5,10 233:23 234:7 235:8 243:20 244:20 248:19 250:3 251:5 253:20,22 254:4 259:1 262:24 ethicons 223:21 228:20 229:6 250:11 eugenia 139:4 evaluate 184:11 evaluated 256:13 evaluating 185:1 event 198:10 264:23 265:3,4 events 162:15 164:12 eventually 182:2 ewhu 250:2 exact 261:19 exactly 189:21 examination 143:6 145:5 255:1 260:8 267:4 examined 165:18 example 230:8 examples 151:9 excessive 161:6,9 198:8,14 219:4 exciting 178:22 exclude 240:14 exhibit 144:5,6,7 144:10,11,14,16 155:21,24 162:19 162:22 181:22 182:5 243:12,15 246:7,10 247:13 247:14,18 256:6 exhibits 144:1 155:22 247:17 expect 166:9	183:15 184:16,19 185:5 expected 190:3 experience 146:19 181:13 193:24 209:8 262:6,15 experienced 237:9 expert 156:7 157:17 164:15,24 170:11 182:4 183:22 184:2,6 186:20 220:24 221:10 262:18,21 expertise 184:13 188:9,20 189:5 experts 221:24 222:14 223:4,5 expires 267:21 270:17 explanation 157:2 157:8,9 explanttype 241:3 exposure 155:6,14 156:14 157:19 158:11 237:20 241:3 extensively 258:21 extent 185:4 extra 156:17 158:3 extrusion 237:5,8 237:20 exuberant 204:6 213:22	152:14 153:14,16 154:6,15 156:1 157:11,15 158:19 158:22 162:20,24 163:3,16 164:22 165:6 167:23 168:2 170:5,19 171:7,14 173:1,11 174:4,19 175:1 176:9,13 177:9,12 178:22 179:2,13 179:18,20 180:21 181:15,23 182:18 183:17,20 185:3 185:12 189:4 190:23 191:5 193:1,3,12,19 194:4 195:8 197:16 198:5,17 199:21,23 200:5 201:21 203:9 204:12,17 207:19 210:8 212:2,10 215:14 217:19 219:5,14 220:8 221:8,23 223:10 223:17,19 225:3,5 225:13,15 226:10 226:14 228:14 229:12,18 230:6 231:3 232:22 233:7 234:6,24 235:18 236:8 238:21 239:4 241:23 242:4 243:13,18 245:8 246:8 247:15,22 248:16 254:15,20 260:6,9 263:5,24 264:5 266:8 fail 268:18 failed 209:6 failure 150:5 151:6 151:19 152:2 186:24 187:4,11 187:16,20 188:1
--	---	--	---	--

211:6,8 213:9 fair 147:15 187:3 201:16 239:20 259:6 263:17 familiar 166:10 167:19,20 185:1 187:1,17 202:8 206:15,21 262:13 far 182:15 184:6,10 184:12 185:10 258:17 261:15 fascias 192:4 fatton 202:9,12 fault 174:22 favorable 182:11 182:16 fax 140:21 fda 169:2 171:8,15 172:3,10,17,22 173:3 193:22 209:13 218:22 219:8 249:3 257:7 257:11,17 261:5 262:1 264:18 fdas 264:13 fear 251:10,16 253:3 fears 234:12 235:14 236:5 248:12,22 249:13,20 250:22 february 163:8 246:15 federal 215:1 feel 155:18 175:12 181:11 184:23,24 189:1,12 210:15 266:1 felt 164:11 251:5,6 fibers 190:17 233:6 253:1 fibrosis 197:19,23 file 138:3 filed 210:22 211:2 211:11 financial 263:9 financially 267:15	find 146:7,10 findings 232:14 238:14 fine 157:22 192:2 194:14 firm 141:17 181:14 first 145:3 157:4 163:12 164:3 165:10 176:2 188:15 207:16 220:12 246:19 259:3 firstline 250:18 five 264:24 265:5 fixation 204:9,10 204:16 flat 231:15 233:2 floor 185:11,15 192:24 195:15 257:11 261:4,8 264:14 floppy 233:6 234:23 folding 244:11 followed 157:7,8 following 138:6 152:19 follows 145:4 213:15 followup 197:1 239:6 247:20 254:19 266:11 foregoing 267:7 270:4 foreign 160:17 183:2,5,6,7,11 forget 145:15 forgot 265:23,24 forgotten 257:1,2 260:1 form 149:18 150:13 151:1 152:8 154:1 154:12 158:15 163:14 164:19 165:3 171:2,13 172:20 173:9,23	180:15 181:9 182:12 184:21 185:8 188:23 192:5,21 193:9,17 194:2 195:3 197:14,22 198:12 200:3 201:20 203:2 207:11 210:4 211:23 212:7 215:11 217:17 219:2,12 220:5 221:5,16 223:7 228:11 229:10,17 230:3 231:1 232:15 233:4 234:3,14 235:15 236:6 245:4 248:14 263:4 270:6 formation 230:1,18 244:7 forming 173:13 180:24 194:21 195:4 forth 267:8 found 175:15 232:12 234:1 236:18 fourth 247:23 248:10 fox 138:20 frame 239:8 france 205:14 frankly 156:13 frcp 267:10 free 155:18 french 204:19 frequency 159:20 front 155:19 163:7 fully 213:15 256:12 function 160:21 176:6,7 228:3,10 funny 156:9 further 260:8 267:6 267:10,12 future 228:15	229:7 fyi 178:19 <hr/> G <hr/> gage 142:2,3 143:8 149:18 150:13 151:1,22 152:8 154:1,12 157:5,13 158:15 163:2,14 164:19 165:3 170:15 171:2,13 172:20 173:9,23 178:19 179:9 180:15 181:9 182:12 184:21 185:8 188:23 192:21 193:9,17 194:2 195:3 197:14,22 198:12 200:3 201:20 203:2 207:11 210:4 211:23 212:7 215:11 217:17 219:2,12 220:5 221:5,16 223:7 228:11 229:10,17 230:3 231:1 232:15 233:4 234:3,14 235:15 236:6 239:1 241:16 242:3 245:4 248:14 254:18,21 255:2,4 260:5 263:4 266:10 gather 148:22 gears 182:19 general 146:12 147:9 183:10 185:10,11,14,16 186:3,5 229:14,22 generally 220:11 227:20 251:22 255:15 gessner 140:8 getting 147:20	give 151:9 179:8 187:9 206:4 given 207:13 228:1 228:7 230:23 270:5 go 148:23 184:22 185:10,19 191:1 226:10 237:13 239:21 241:10 244:1 253:12 254:15 goal 228:22 229:6 249:19 goes 184:12 197:18 going 146:4 147:10 153:14 156:20,24 157:1 158:19,23 159:1 162:21 166:12 167:23 169:7 173:21 174:19 176:9 177:9 178:17 179:3,4 181:20 182:1,1,3,19 183:7,17 190:2,8 190:10,16 196:19 201:8,13,17 203:15 204:5,12 209:23 223:15 229:19 234:19 235:1 236:9 238:23 241:9 242:21 243:14,24 246:9 247:16 249:8 250:23 258:19 259:7 263:24 264:2 golkow 140:21,22 good 166:11 174:1 174:10 190:5,13 203:7,15 229:4 251:12,18,19 goodwin 138:4 google 250:2,10,12 grade 260:20 261:1 grades 260:14
--	--	---	---	---

graft 154:4	hand 162:21	high 207:3,15	256:20,21 259:18	implanted 258:23
grand 141:3	243:14 246:9	209:6 236:19	260:10,12	implanter 240:22
great 194:14	247:16	242:17 257:18	ifus 164:1 172:17	implanting 165:10
199:18 207:14	handicapped	highland 142:3	ii 260:14	234:16
greater 183:11	179:16	highrisk 207:6	iii 209:15 260:14	implants 216:10,21
189:16 191:20	handing 256:4	209:15	ill 157:11 163:4,22	240:24 258:5
groin 161:18	hands 184:23	hilaire 144:13	164:23 167:12	important 165:19
group 204:20 205:4	185:20	hill 138:8	174:23 176:11	166:18 167:2
247:24 248:2,6,9	hang 157:5	hold 171:17 183:22	188:11,17 191:12	168:13,20,20
253:13,21 262:3	happened 222:23	184:2 186:19	193:1 196:4	169:2 173:13
guess 174:14	happens 196:16	188:8,20	206:24 207:4	174:3 176:5
188:11 254:18	harm 217:5,13	honestly 247:1	224:19 239:1	189:15 222:20
guidance 192:13	harmful 252:22	hot 158:18	245:11	248:22 249:12,19
215:1	hate 241:7	hour 243:4,7	im 150:1 153:14	266:2
guide 177:14,17	havent 168:11	hours 241:12,14	154:16 156:20,24	impossible 181:19
guideline 195:11,17	170:16 180:17	242:5,8,13,16,24	157:1 158:19,23	improve 244:15
gynecare 144:5,6	209:6	houston 140:7,8	159:1 162:21	incentive 263:9,15
256:12	hazardous 252:7	141:19 239:24	163:15 165:20	264:8
gynemesh 144:6	head 202:14 262:12	human 252:7,23	167:23 168:22	incidental 147:6
147:16 151:14,15	heal 189:24 190:4	hypothetical 149:7	174:19,20 176:9	include 163:18,24
151:21 153:10	204:6 213:21		177:9,21 178:15	259:10
159:2 162:5,11	healing 183:16	I	178:17 179:3,4	included 162:4
163:6,11 164:1	234:21 244:9	ideally 226:5	181:20 182:1,3,19	240:19
165:24 166:3,4,7	health 144:12	ifu 144:5,6 145:13	183:17 186:16,17	including 161:12
167:9,16 168:10	209:16 250:3	147:20,22 149:22	187:1,17,23 188:3	161:17
169:11 170:11,17	251:7 252:7	150:3 151:13	188:7 195:4,13	incontinence
170:21 173:4,7,18	heather 139:13	154:24 155:11,15	201:5 204:12	159:12,16 192:19
177:24 178:5,9	held 140:7 184:8	155:19 156:8	206:20 209:23	incorporate 189:24
180:10 182:8,22	help 244:10	157:18 162:5,11	210:6 214:17	192:7 197:24
187:6,21 188:5,12	helpful 158:13	163:6,19 164:8,12	216:12 220:21	incorporated
188:13 196:1,8	166:24 174:15	164:17 165:1,9,14	229:19 231:2	189:18 190:22
198:7,11 205:5	hematoma 159:8	165:15,18,19	234:15 235:1	191:17 199:1
214:6,6,16 217:21	hemorrhage 159:8	166:7,17,20 167:1	243:14,24 246:9	incorporation
219:9,18,23	hereinbefore 267:8	167:3,9,16,18	247:16 249:8,16	190:5,13 244:16
223:13 224:7	herman 141:11,11	168:1 169:16	254:16 256:4,6	incorrect 188:24
226:19 228:18	hernia 145:16,18	170:7,8 173:19	263:24 264:2	increase 212:19
229:1,9 231:15	145:21,24 146:11	176:2,6,7 177:6,8	imagine 152:11	213:5,8 228:2,8
232:24 233:9,17	146:11 192:13	177:14 178:12,14	172:21	increased 227:24
234:1,9 235:10,21	193:21,24 226:21	198:7 214:20	impact 203:12,15	228:7 244:12
236:1,12 258:8	hernias 146:9,17	215:3,8,16,21	227:24 228:6	indepth 189:13
259:18 265:22	146:24 147:5	216:1,3,7,18	258:17 265:12	index 143:1
266:4	hes 199:15,24	217:1,9,21,22	impair 160:20	indicate 246:21
	201:13	218:2,4,4 219:11	228:3,9	254:8 258:3
H	hey 218:2,14 220:2	220:11 255:7,10	imperative 268:14	indicated 169:12
hagans 139:2	220:17	255:11,21 256:5,7	implant 155:6	169:21 173:7
half 232:18 245:19	hhklawfirm 141:12		169:8	207:23 218:16

255:19 260:24 indicates 256:21 257:24 indicating 201:24 indication 170:2 171:5 173:6 174:12 218:24 219:1,11,23 indicationforuse 173:20,22 indications 168:14 168:24 169:15 170:12,20,23 172:15 175:22 176:15 177:1,14 178:11 218:14 219:18 220:2,18 255:17 259:17 265:21 indicationsforuse 260:11 individual 241:18 241:22 individuals 207:7 211:10 254:10 inflammatory 183:3,12 244:8 inform 166:16,24 information 152:3 155:1 156:8,17 158:3,7,10 214:21 215:3 216:6,11,15 216:17,22 222:18 223:2 240:10 260:3 informed 166:7 informing 218:13 219:17 220:1 260:23 informs 260:18 inguinal 146:11 inhalation 252:24 inhaled 253:5 initial 246:22 247:4 inject 206:2 injected 201:9	instances 204:1 instruction 175:19 instructions 268:1 integration 194:10 194:18 195:11,19 intellectual 199:19 199:20 intend 236:15,21 237:6 intended 176:22 intensity 183:2 intercourse 161:2 interested 267:15 internally 197:12 intraabdominal 170:2 intrinsic 253:15 invention 199:18 inventor 199:3 201:7 205:9 206:1 investigator 201:11 201:12 206:5 investigators 201:2 invoices 241:8 involved 184:7,10 204:7 206:3,11 222:10 isd 253:14 isnt 166:13 210:5 241:2 245:21 issue 148:24 213:13 263:22 issued 257:16 issues 148:11 257:12 issuing 209:15 iv 255:12,22 256:13 256:20,22 260:20 261:1 ive 180:2,3,17 184:9 189:10,11 195:6 204:23 255:4 260:3 <hr/> J <hr/> jane 138:14 242:9	january 247:19 jean 139:23 jo 139:16 johnson 140:10 267:2,18 joint 206:16 joseph 138:4 joy 138:6 judge 138:5 judgment 208:24 209:1,3 judiciously 152:23 153:24 154:3,5,8 154:10,14,19,20 <hr/> K <hr/> k 138:18 kansas 141:4 katz 141:11 keep 173:3,5 238:17 kept 253:7 key 139:19 kind 168:3,6 215:2 219:22 239:5 240:17,22 242:11 kit 207:2 kits 171:4 184:3 185:11,15 186:2,8 186:9 207:6 knew 147:22 148:3 152:3,5 163:11 165:4 168:18 169:5 259:22 265:21 know 146:3 149:5,8 150:11 155:18 156:12,13 162:10 162:14,18 163:9 163:15,17,23 164:10,13 165:4,5 166:2 167:5,17,18 168:22 170:9,10 171:5,8,15,20,22 172:4,22 173:2,10 173:20 174:3,6,15	175:3,7 177:4,5,6 177:11 181:6 182:23 186:23 187:15,24 190:1,7 190:9 192:9,12,16 192:22 193:4,6,10 193:13,18,20,22 194:3 197:10,15 199:3,9,12,14,15 199:24 200:4,6,10 200:16,17 201:1 201:15,19 205:8 205:16,19,20,23 206:22 210:21,24 211:19,24 212:3,8 212:11 214:24 215:6 217:6,14,18 218:8,10 219:7,15 219:20 220:16 222:18 223:3,8,9 223:11,20 224:4,8 226:19 229:5,11 231:4,10,14,17 238:18 239:2 240:16 241:13 244:23 245:6,12 247:8 250:3 251:24 252:2,5,8 252:9,14,19,19,21 252:24 253:10 254:12 261:12,16 261:19,21 262:2,7 262:17,20,22,23 263:3,17,21 264:10 265:11 266:2 knowing 165:18 knowingly 164:16 165:1 knowledge 157:24 162:7 188:9,21 189:6,13 199:19 knowledgeable 189:1 knows 167:7,14 168:9	kott 141:12 kriz 138:9 <hr/> L <hr/> l 141:6,6 la 141:6,7 label 174:7,8,17 175:4,8,12,14 178:2 labs 184:8 lacerations 161:10 laparoscopic 169:23 laparotomy 169:23 large 191:23 largepore 229:14 229:22 230:15 larger 183:10 244:5 245:1,13 laser 231:24 232:7 232:11 258:9,15 265:13,16 lateral 244:13 launch 200:8 221:1 221:3,11,13 222:1 222:5,15 243:22 246:16,23 launched 163:12 164:3 laundry 164:7 law 141:17 lawsuit 251:10 lawsuits 210:21 250:22 251:16 252:10 lawyers 143:14 241:18 271:1 lay 192:6 lead 200:6 201:10 213:17 244:6 learn 177:7,8 185:24 200:19,20 learns 217:2,10 leave 181:20 leg 161:18 legal 207:13,17
---	---	---	--	---

208:21 209:10 210:19 211:11 length 160:21 lesser 230:23 letter 144:11 217:24 218:1,13 218:20 219:16 level 180:18 257:18 leverage 193:24 liability 138:4 liaison 241:20 ligament 204:9,10 204:16 lighter 245:1,6,14 lighterweight 245:17 lightweight 244:3,4 limit 254:17 line 252:10 269:2 271:3 list 144:7 158:24 164:7 179:22,24 180:5,7,8 182:4 listed 246:18 248:1 literature 174:10 174:18 179:22 180:6,9,17,18 181:4,12 192:24 205:3 209:8 257:23 litigation 138:4 238:19 250:6,12 250:15 259:2,24 262:18,21 little 174:23 176:12 182:20 192:2 196:19 217:21 235:3 249:8 254:22 live 176:6 llc 141:11 llp 141:2,17 142:2 lodged 236:2 log 238:16 logan 139:20 logs 237:14	lois 138:21 long 139:13 152:9 164:6 258:24 longer 171:9 218:15 251:22 longitudinal 244:12 longterm 248:11 look 162:17 172:17 177:6 196:14,15 196:15 202:18 206:18 215:23 232:16 237:13 238:9 248:8 254:13 looked 191:11 265:15 looking 179:15 191:12 204:24 235:7 looks 246:24 250:24 lost 239:6 lot 156:22 177:7 182:7 208:7 210:16 259:7 262:5,14 263:19 louisiana 141:14 low 242:17 lower 192:5 230:1 230:1,17,18 lucente 262:11,20 262:23 263:7 lung 253:1 lynn 144:14	machine 231:6,8,12 258:9,14 macro 192:3 main 195:13 mainstream 262:4 262:8 maintaining 244:13 major 263:12 majority 195:15 making 150:19 248:19 manufacturers 211:11 march 138:10 140:2 143:2 144:2 267:22 marcus 199:5 maria 139:4,17 marie 138:18 mark 178:17 marked 144:4 155:20,24 162:19 162:22 181:22 243:12,15 246:7 246:10 247:13,14 247:17 256:5 market 163:13 171:1 172:19 173:4,5 221:2,12 222:2,16 252:10 marlex 230:9 mary 138:14 242:9 master 138:3 material 169:21 183:11 materials 144:8 186:7 202:10 214:11,15,19 215:5,9,18 216:7 259:7 matter 190:17 232:21 257:14 matters 194:23 195:2 266:6 mcdonalds 158:17	mdl 138:6 144:9 mean 148:1 167:10 168:19 196:10,12 215:22 221:18 meaning 198:22 meant 245:7,9 mechanical 187:12 231:24 mechanically 232:21 265:13,17 medical 145:22 168:15,17 169:1,4 174:7 175:3,22,24 176:15,17,19 177:1,2 179:22 180:6 183:23 184:3 186:12 208:23,24 209:2 220:24 221:10 222:12,14 228:20 231:22 252:13,15 252:18 259:14 meeting 247:20 251:4,5 member 261:9 members 262:8 memorial 140:7 mentioned 170:16 258:19 mesh 147:4,11 148:7,16,19 149:12,24 150:4 150:20 151:12 152:3,5,23,23 153:4,5,12,18,22 153:24 154:4,5,9 154:10,11,14,20 155:6,6,14 156:14 161:7,9 167:20 170:12,21 172:15 182:21,24 183:5 185:10,14 186:2,3 186:5,5,7 188:10 188:12,14,22 189:2,2,3,7,11,15 189:17 190:7,10	190:11 191:18 192:8,18 194:7 195:18 196:12,20 197:18,19,21,24 198:1,2,3,6,9,15 198:19,20,22,24 199:2 202:4,6 203:19,21 204:2 204:11,19,22 207:2,6 208:9 209:4 210:20,21 211:2,5,7,12 212:18,23 213:4 213:17 218:15,16 223:12,22 224:6 224:18,20,22 225:2,12 226:1,6 226:21 227:9,13 228:1,7 229:2,3 230:7,8,9,10 231:4,7,10,14,18 231:19,23 232:2,7 232:11,12 233:3,9 234:1,10,17,18 241:3,3 244:4,9 244:10,24 245:2 245:13,14,18,20 248:23 249:14,21 254:5,10 257:13 257:20 258:1,4,8 258:13,20 259:2 261:8 262:15,18 262:21 263:1,10 263:14,16 264:7,9 264:13,14,21 265:14,17 meshes 147:12 228:13,16 229:7 229:14,16,22,24 230:4,15,17 232:12 244:6 mesothelioma 252:9 met 199:7 205:12 method 231:18,23 micheal 140:10
---	---	--	--	--

267:2,18	N	news 178:22	197:14,22 198:12	153:5 154:23
microns 191:20	n 141:1,2 142:1	night 145:12	199:21 200:3	159:3 168:23
194:23 195:12	name 206:22,23	nonresponsive	201:20 203:2	177:20 182:6
microscopic 190:15	246:18,18 248:1	264:1	204:12 207:11	197:3 206:24
migrate 204:3	255:3	norm 146:11 203:4	210:4 211:23	230:11 235:1
mikalia 141:12	named 251:10,16	normal 160:20	212:7 215:11	240:24 241:5
millimeter 189:16	nancy 139:16	183:15	217:17 219:2,12	242:3 245:10
189:21 190:20	native 152:21	notary 140:12	220:5 221:5,16	246:6,12 249:10
191:15 194:13,14	nature 169:8	267:3,20 270:20	223:7,17 225:3,13	254:18 256:4
194:17	ncra 267:18,19	notebook 179:10	228:11 229:10,17	okeefe 141:13
millimeters 194:8	near 189:23	noted 268:11 270:7	230:3 231:1	olsen 138:14
million 200:1	nearly 170:13	notes 143:14 271:1	232:15 233:4	olson 242:9
205:21 262:24	necessarily 151:2	notice 140:6	234:3,14 235:15	once 189:18 217:1
263:7,14 264:7	151:23 152:10	notification 209:16	236:6 242:2 245:4	217:9 220:11
mind 261:15	162:8 175:5,10	249:3 251:7	248:14 263:4,24	op 178:23
minimally 196:22	183:14	notify 172:3	objection 151:22	operative 237:14
minimum 194:17	necessary 164:11	nuance 177:21	170:15	238:16
mississippi 142:4	190:19 191:14	nuances 186:9	obligation 217:7,15	opinion 152:1
missouri 141:4	218:6 219:4 220:7	number 144:4	observed 245:17	153:17,21,23
mistake 221:1,11	220:13,22 268:4	210:24 238:1,2,5	obstruction 159:21	154:2,7 155:10
221:18,22 222:1	need 146:9 153:3	239:10 241:12	160:1	156:2,6 157:16
222:15 223:6	157:2 172:3 179:6	257:4 261:20,21	obviously 221:18	162:2 173:16
mkott 141:12	179:8 182:1	262:2	occasionally	175:16 191:23
mode 187:4	189:23 190:24	numerator 238:6	146:10	195:4 206:16,16
modes 186:24	195:18 241:10	numeric 236:22	occur 161:13,19	207:1,5,10 208:2
187:16,20 188:1	263:21	237:3,7	194:10,18 204:8	208:4,5,13,17,20
moment 169:14	needed 155:2 194:8	numerical 195:16	213:19 223:12	209:1,11,17
monocryl 245:16	194:16 195:10	O	225:11 228:12	214:18 231:21
monograph 213:24	240:7 251:6	ooo 266:14	occurred 150:2	236:10,15 237:6
monograph 214:7	253:22	obese 254:6,10	151:18 170:7	253:2,11 266:3
214:19 215:4	needs 155:3 191:24	obesity 253:16	218:9	opinions 154:17
216:6,15,17	negative 208:9	object 149:18	occurs 202:5	170:11 173:14
monographs 215:8	negotiated 173:3	150:13 151:1	212:23 264:24	180:14,20 181:1,6
215:17	neither 267:13,14	152:8 154:1,12	265:4	181:13 184:19,22
months 202:17,24	nerve 160:11	158:15,20 163:14	offer 157:2 184:16	185:5,9,13,18,24
morrow 139:22	161:11 204:6	164:19 165:3	184:19 185:5	186:1,4 194:21
motivation 221:4	network 257:15	167:23 171:2,13	186:1 236:10,10	205:4 210:19
221:14 263:23	261:8 264:14	172:20 173:9,23	236:16,21 237:6	222:24 238:23
move 153:14	neuromuscular	174:19 176:9	238:23 242:22	241:10 242:22
158:19,20 167:24	161:16	177:9 180:15	offering 170:11	257:6
174:20 176:10	neutrophiles	181:9 182:12	241:10	opportunity 185:23
177:10,10 183:18	189:21 192:3	183:17 184:21	offers 176:21	option 152:22
193:1 199:21	never 187:4 205:14	185:8 188:23	offlabel 174:12	207:16
204:13 223:17	227:19 252:13,17	192:21 193:1,9,17	oh 204:4	options 207:7 222:4
225:3,13 264:1	new 141:14 166:17	194:2 195:3	okay 146:14 149:17	oral 138:8 140:5
multiple 147:8	167:1,7,14 244:14		150:22 152:7,15	order 171:11

189:17 190:21 191:16 194:9,18 195:19 203:7 organ 179:5 191:18 192:18 194:1 209:14 226:3,8 227:10 228:17 229:8 246:2 248:24 249:15,22 250:16 255:12 256:14 257:12,20 259:1,23 264:20 organization 261:10,13,17,24 262:9 264:19 organizations 261:5,6 264:12 organs 161:11 original 240:21,22 245:2,15 268:15 originally 192:13 193:21 orleans 141:14 outcomes 230:24 outdated 193:8,15 outlier 262:1 overall 220:23 221:9 222:11,13 overnight 145:8	parameters 185:2 parkway 142:3 part 162:6 183:16 188:15 participated 253:21 participating 248:2 248:5 particles 235:20,24 236:2 particular 168:15 169:1 222:2,15 255:9 262:10 particularly 167:4 258:2,18 parties 267:13 party 267:11 patient 153:2,18,22 154:11 184:24 189:9 200:24 203:13 213:20 229:15,23 230:16 234:21 236:20 240:10 248:9 259:14 patients 153:3,4,11 153:13,24 161:2 186:10 189:12 190:4 204:5 207:14 208:8 222:17 223:2,9 237:3 239:6 240:14,19,21 248:12,23 249:13 249:20 256:13,15 262:16 265:5 paula 138:9 pay 250:10 pelvic 138:3 155:8 155:13 156:10 157:20,24 158:12 159:6,10,14,18,23 160:3,6,9,12,15 160:18,23 161:1,4 161:14,18,20,24 162:7 167:11,12	167:13,19,20 168:8 176:24 179:5 185:11,15 191:18 192:18,24 194:1 195:15 203:4 209:14 223:15 226:3,8 227:10 228:17 229:7 246:2 248:24 249:14,22 250:16 255:12 256:13 257:10,12 257:15,19 259:1 259:23 261:4,7,15 262:15 264:13,14 264:20 pelvis 182:24 pending 191:11 penny 139:14 people 230:22 254:5 262:13,14 263:19,20 264:24 percent 200:18,21 201:3 202:17,23 203:5,8,11 percentage 204:20 237:7 perfectly 197:6 213:16 performance 150:4 150:21 152:7 person 263:13 264:6 personal 200:10 236:11,16 257:23 personally 237:9 perused 180:2 peter 141:7,7 ph 140:21 physician 146:18 174:6 175:2 177:24 178:5,9 215:10,18,21,23 216:2,9,21 219:7 252:6 physicians 175:6	214:22 218:1,13 218:21 219:17 220:1,16,21 224:5 225:20,23 235:14 235:17,19,23 236:5 251:5 260:19,24 261:6 262:1,2 263:18 pick 182:14 place 177:24 178:5 178:9 244:10 267:8 placed 171:17 172:19 182:24 183:6 189:19 196:13,20 197:5 211:16 212:23 219:1 234:20 252:22 placement 169:12 171:6 173:8 218:16 placing 216:1 plaintiff 141:10,20 plaintiffs 141:5,15 plan 236:10 246:16 plane 212:24 234:21 plans 171:16 plating 197:11 please 150:23 157:4 215:13 217:8 221:7 228:4 251:14 268:3,8 pliability 244:14 plication 204:8,15 point 170:3 190:12 207:12,21 208:1,3 210:23 243:2 248:10 250:1 253:13 265:16,21 poking 234:19 polypropylene 147:4 244:4 poor 234:21 pore 189:7,11,16	190:19,20 191:14 191:15,20,24 194:7,23 195:1,7 195:10,24 196:7 196:16,21 197:6 245:1 pores 186:6 190:2 190:12 195:18 244:5,24 245:5,13 portion 207:1,5 posed 255:16 position 175:14 239:2 positive 203:21 226:24 possible 166:13 180:12,16 181:4 181:17 200:23 226:9 259:21 260:2 261:24 postoperatively 228:2,9 postponed 178:20 potential 159:2 160:20 198:10 206:2,10,13 228:3 228:9 233:14,18 234:2 236:4 244:20 potentially 185:21 213:11 235:12 potts 141:17 pottslaw 141:18 practice 145:17 146:16 165:9 175:19,21 176:14 176:24 186:22 195:6 196:18 234:5 239:22 pramudji 138:9 140:6 143:1,6 144:1,7 145:2,7 226:15 255:3 267:4 270:4,12 precautions 256:7 256:11
--	--	--	--	--

precede 250:6	171:1 182:11	206:12 209:19	protrude 233:19	196:12 197:8
preceptors 246:22	192:20 194:1,8	210:1,5,9,16	235:12	216:5,14,16
247:4	209:14 210:21	214:2,8 231:5,8	provide 150:5	217:22 218:2
presence 225:12	211:12 236:13,17	233:1 236:12	151:6,19 158:9	219:22
present 263:8	236:19 237:1	237:12 239:10	215:2 229:15,23	puts 156:7
press 243:21	239:13 240:5	240:2 243:22	230:16	putting 253:4,7
prevented 253:4	professional	244:3,21,24 245:2	provided 152:3	
prevents 251:10,16	214:10,15,19	245:12,15,20,23	providing 158:6,10	<hr/> Q <hr/>
previous 150:18	215:4,9,17 216:7	246:1 258:8 266:4	214:20	quantitative
166:20 167:3	216:18	proper 194:9,18	ps 144:6 147:16	195:17
244:6	professors 262:14	195:10,19 212:24	151:14,15,21	question 145:15
previously 217:3	profit 221:4,15,20	properly 189:18	153:10 159:2	146:15 148:12
217:11 218:4	prolapse 146:8	196:20 230:13	162:11 163:6,11	149:6,11 150:8,12
price 144:12	160:14 169:22	properties 182:21	164:2 165:24	150:16,18,23,24
primary 177:18	179:5 183:1 184:4	244:9	166:3,4,7 167:9	152:9 156:21,21
265:16	191:18 192:19	property 199:20	167:16 168:10	157:1,4 163:22
prior 173:19 200:8	194:1 209:14	propounded 270:6	169:11 170:11,21	164:20 174:23
209:7 259:22	224:10 225:18,22	prosimas 144:5	173:4,7,18 177:24	176:11 177:5
267:3	226:3,8 227:10	145:13 148:7,16	178:5,9 180:10	188:16 191:11
probably 179:14	228:17 229:8	149:12,22 150:7	182:8,22 187:6,21	194:15 195:23
180:11 187:12	230:23 246:2	151:21 152:20	188:5,12,13 196:1	196:4,6,23 197:2
208:6	249:1,15,22	153:1 154:24	196:8 198:7,11	206:8 209:23
problem 152:13	250:17 255:12	155:11,12,19	205:5 214:6,6,16	210:7,14 213:2
156:18 162:13	256:14,22 257:13	156:13 157:18	219:9,18,23	214:5 215:12
223:21	257:20 259:2,23	159:3 162:5	223:13 224:7	216:13 221:6
problems 161:16	260:14,20 261:1	163:10 164:2	226:19 228:18	229:20 230:12
procedural 224:1	264:21	168:10 170:23	229:1,9 231:15	235:2 237:4 241:6
procedure 209:7	prolene 226:21	171:10,16 172:9	232:24 233:9,17	241:19 245:11
212:19 213:5	227:9,13 230:8	172:13 180:9	234:1,9 235:10,21	246:14 249:7
proceed 145:9	231:18,23 266:4	182:9,22 184:20	236:1 258:8	252:16 255:16
177:22 191:8	prolific 262:5	185:6,6 186:2	259:18 265:22	258:2 260:1 264:3
226:17	proliferate 145:13	187:5,21 188:6,11	266:4	questions 144:16
proceedings 145:1	148:7,16 149:12	188:22 194:7	public 140:12	179:5,15 182:21
process 172:22	149:22 150:6	196:1,8 197:5	209:16 251:7	197:1 210:16,18
187:15,20 197:18	151:21 153:7	199:4,11,16 200:1	267:3,20 270:20	241:24 246:4
processes 197:20	159:2 162:4	200:7,12,22 201:3	published 205:3	247:11 255:5,6,10
produced 184:12	163:10 164:2	201:9 210:14	pull 213:21	255:13 257:5,8
238:19,22	168:10 170:24	211:16,22 212:6	pulling 213:11,12	258:7,10 260:7
product 166:11	171:10,16 172:9	212:17 213:5,16	punctures 161:10	266:9 270:6
201:7 215:10,19	172:14 179:19	214:1,11 230:22	purpose 221:19	quick 187:9 190:24
215:22 218:22	180:10 182:9,22	231:11 233:1	pursuant 140:6	226:11 246:13
220:12 222:9	187:6,21 188:6,11	236:12 239:11	267:10	quijano 139:4
251:11,17 252:10	188:22 194:8	246:15,23 247:4	put 146:5 156:9,19	quite 258:21
253:5,7	196:2,8 197:5	255:6,11,18,21	157:22 164:7,9,16	
products 138:4	204:21,22 205:5	256:5,12,20 258:8	165:1 171:6	<hr/> R <hr/>
166:3,18 167:1	205:10,17,22	260:10,13	172:19 190:1	r 138:4 141:1,17

142:1 ramp 250:20 ran 155:22 rare 257:23 258:1 264:21,24 265:2,8 265:10 rarely 177:8 rate 200:11,22 201:3 202:17,24 203:1,11 236:11 236:16,22 237:3 237:16 239:10 240:20 243:2,9 rates 237:5,8,11,17 237:19,21,24 238:15,24 239:9 240:13 rdr 267:18 reach 215:9,18 reaches 215:21 reaction 155:11,16 156:4 157:18 158:10 183:3,8,12 183:15 reactions 158:14,24 161:23 166:19 167:2,8,15,22 168:9 216:19 218:3 reactive 244:7 read 150:10,12,22 150:24 162:3,15 164:20 165:9 169:15 175:19,22 176:15,24 179:24 180:3 187:14 215:23 220:3 256:16,23 268:3 270:4 ready 145:9 191:7 226:16 real 246:13 really 153:3,11 157:23 174:13 177:17 179:8 222:8 250:19	253:2 258:16 realtime 140:11 267:2,19 reask 156:20 188:17 196:4 209:24 235:2 245:11 249:9 264:2 reason 209:10 218:21 219:8 229:24 230:17 268:5 269:4,6,8 269:10,12,14,16 269:18,20,22,24 reasonable 166:16 166:21 168:16 169:3 170:22 172:7,12 203:8 209:22 210:3,12 217:24 218:6,7,12 218:17,18,20 219:3,6,22 220:4 220:6 231:22 reasons 146:5 recall 146:21,23 147:2,3,12 151:16 187:19 188:4 202:1,16,19,21 214:3,9,14 223:23 232:8 237:12 238:8 242:5,7,8 249:5 251:3,4,8 255:7,13,15 257:7 258:10 259:2,19 receipt 268:16 receive 201:8 received 205:21 206:1 262:24 263:7 receives 199:10,14 205:17 recess 191:3 226:12 254:23 reclassifying 209:14 recommendation	248:18 253:24 recommendations 248:9 250:9 253:13,20 254:4 recommended 256:15,22 record 145:8 179:1 182:5 191:2,7 226:11,16 records 259:14 recurrence 224:10 225:17,22 recurrent 160:14 reduction 244:8 redundant 156:10 156:17,24 refer 146:18 155:19 179:6 reference 256:3 referenced 144:8 255:11 references 255:21 referring 148:11 150:15 230:5 regard 152:20 153:7,10 155:15 183:23 184:3 195:9,9 199:16 214:5 216:19 232:5 237:4,7 244:3 248:23 249:13,20 255:21 257:19 260:10 regarding 151:13 152:24 188:10,21 189:6 201:17 204:20 210:20 238:14 242:13 243:21 247:19 regards 216:8 region 246:17 registered 140:10 267:2,18 regulatory 215:1 related 148:18 255:10 257:12	263:1 relates 138:5 relative 267:13,14 release 243:21 released 163:7 235:20,24 reliance 144:7 179:22,24 180:7 182:4 202:10 relied 205:2 relies 195:15 rely 177:18 relying 191:22 195:12,14,17 remark 155:21 182:3 remember 155:20 239:15,19 240:5 242:10 247:1,3,6 247:10 248:5,18 248:20 249:23 255:24 259:5 262:10,12 reminder 158:16 158:21 reminding 158:13 remove 173:6 218:23 219:10 rendering 266:3 reoperation 237:11 237:17,18,24 238:24 239:9,10 240:8,13,15,20 241:4 reoperations 238:2 241:1 repair 138:3 146:1 146:9,13,16 147:4 152:21 161:13 192:14 193:21 203:7 258:3 repaired 146:24 147:8 repairing 146:8 repairs 145:16,18 145:22 152:24	154:10 209:4 226:21 repeat 150:8 164:21,23 188:15 215:12 216:12 217:8 221:6 228:4 230:12 249:16 251:13 rephrase 224:19 report 144:8 178:24 179:6,21 179:23 180:7 182:9 191:12 202:23 reported 200:11,21 201:2 202:16 204:19 reporter 140:11,11 150:10 155:22 179:7 267:2,3,3 267:18,19,19 reporting 201:18 206:10 225:20 reports 182:4 represent 163:4 206:24 207:4 representation 152:5 represented 151:13 reps 166:2 requested 267:11 require 161:13,23 required 190:21 191:16 rereview 165:14 research 168:4,7,11 residency 147:8 resists 244:11 resolve 161:3 resource 214:7 respect 187:5 responding 243:21 response 160:17 183:3,12 244:8 restate 167:12 191:12
---	--	---	---	--

restroom 191:1	163:19 164:1	224:23,24 225:6,9	177:19 230:22	261:23 264:16
results 166:12	214:21 216:8,19	225:16,21 230:1	sentiment 249:4	site 200:13,14,22
174:2,10,17	233:24	230:17 244:7	set 178:16 267:8	201:4
184:24 222:21,22	road 140:8	scarring 197:24	sex 225:10	sitting 151:16
229:4	robert 243:20	213:12	sexual 228:3,10	situation 174:13
retained 259:3	robin 139:7	science 195:15	shared 240:10	situations 149:1,16
retention 159:21	robinson 144:16	scientists 193:7,14	sharon 138:12	151:5 152:11
return 268:14	rough 238:5 240:18	194:5 197:13	139:5 241:15	sixth 248:1
reverse 240:18	240:23 241:11	233:23	242:6	size 186:6 189:7,16
review 162:12	royalties 199:10,14	scissor 258:23	sharp 233:2,5,9,16	189:23 190:19,21
176:2 202:13	199:16 200:1	scissors 232:24	233:18 234:9,10	191:14,16,20,24
220:11 238:11,14	201:8 205:21	233:10,17 235:11	235:9,11	194:7,23 195:1,7
243:4	206:2	235:22 236:1	sharper 233:11	195:10,18,24
reviewed 187:4,19	royalty 205:17	se 261:13	234:17	196:7
188:5 259:7,14	rule 267:10	searches 250:12	sheet 268:6,9,12,15	sizes 189:11 196:16
reviewing 169:17	rules 157:6,13	second 157:5	270:7	196:21 197:6
reviews 169:19	215:1	226:11 246:16	sheets 231:15 233:2	skills 176:4,8
243:17	run 190:24	250:1 256:10	sherry 138:20	small 145:24 146:8
revision 163:6		section 155:11,16	shift 182:19	146:17 190:12
rhynhart 139:14	S	156:4 157:18	shively 139:19	smaller 189:22
ricks 141:17	s 138:5 141:1 142:1	158:11 256:7	141:15	192:2,4 194:13
riddell 138:11	sacrospinous 204:9	259:17 260:12,15	short 191:7 226:16	smith 138:18
ridgeland 142:4	204:15	260:18,23	shouldnt 260:19	smoked 254:6,11
right 151:17 165:11	safe 205:5 209:4	see 177:20,20	show 222:22	smokers 253:16
195:20 204:24	222:3	180:13,23 181:7	229:14,22 230:15	snow 142:2
209:2 212:14,20	safety 174:10	184:14 229:3	showing 222:21	soft 226:3 234:23
232:9 234:20	248:11,23 249:13	234:5 244:17	256:6	266:4
237:12 238:9	249:21 253:16,22	246:17,19 247:20	shrinkage 161:7	sold 172:9,14
239:19 245:22	254:1 265:15	247:24 248:2,13	198:9,14 202:4,17	199:11 201:9
249:2 251:23	sales 166:2	248:15 250:1,7	202:24 203:1,5,6	218:22 219:9
264:15 265:18	sandra 138:17	253:16 256:8	203:11,19 204:1	222:17 251:23
rigid 228:17 229:8	satisfaction 236:20	263:11,22 264:8	sic 158:9 240:7	soliciting 208:8
rigidity 228:1,7	saw 180:13	seen 180:17 189:11	sign 268:8	solve 223:22
231:19 232:2	saying 221:22	195:6 201:22	signature 267:10	somewhat 184:5
rigorous 182:16	says 169:20 177:20	202:1 204:23	signed 261:11	190:2
risk 155:5,13	178:14 198:13,13	214:3 232:4	significance 196:1	sorry 163:21
156:14 159:4,9,12	207:5 244:2,4	262:15	196:7 197:11	216:12 235:5
159:16,21 160:1	250:2 253:14,23	selection 200:24	256:18 258:13	249:16 264:4
207:15 209:6	254:7 256:11	sell 171:9,18	significant 180:24	sort 156:17 158:17
212:20 213:6,8,10	260:12	selling 172:2	181:7 203:1,12	177:19 187:13
217:2,4,10,12	scar 192:7 197:11	251:17	217:4,12	240:24
233:14,18 234:2,9	197:19 198:2	semantics 174:13	signing 268:10	sounds 187:10
risks 155:8,12	199:1 203:5,6	198:24	simply 174:12	203:8 219:4
156:12 157:20	204:6 213:22	send 217:24 218:12	sit 149:10,16	245:22
158:12 159:2	223:11,15,24	219:16	202:19 232:8	source 215:3
162:3,11 163:5,10	224:7,9,12,15,19	sense 152:22 154:9	238:8 242:12,20	southern 138:1

246:17 space 268:6 speak 220:20 263:23 speakerphone 141:8,13,18 speaking 220:21 specialized 188:9 188:21 189:6 specific 149:9 151:8 154:24 155:1 239:17 241:24 specifically 171:4 195:22 196:5 198:8 249:5 264:17 265:15 spelling 202:11 spent 241:12,14 242:6,9,14,23 sphincter 253:15 spill 158:18 spin 201:17 sricks 141:18 st 144:12 stage 255:12,18,22 256:13,20,22 stance 264:13 standard 191:23 192:9,17 193:8,15 193:20 194:22 229:15,23 230:4,7 230:8,9,16 stands 250:3 start 148:21 163:22 172:2 234:19 started 208:7 239:13,18 240:1 state 140:12 239:17 265:11 267:21 268:5 stated 178:12 190:7 190:9,18 191:13 202:3 210:18,19 250:14 statement 150:3	152:20,24 207:18 256:19 257:22 statements 257:16 states 138:1 164:4 168:9 178:2,10 210:22 211:10 248:11 stenographically 267:7 stephen 141:17 sticker 220:1 stiff 224:24 226:7 226:20 227:20 228:13 229:3 stiffer 232:13 stiffness 224:16,17 224:18,20,22 228:2,8 229:1 230:2,18 231:19 232:2,6 stone 139:17 stopped 239:18 240:4 strain 195:24 196:3 196:7,11,17,19 197:8 street 141:8 stress 192:19 196:13 stretch 197:7 stretching 187:12 strike 152:16,18 153:15,19 158:7 158:20 165:7,22 166:14 167:24 168:4 172:10 174:20 175:16,19 176:10 177:10 178:6 183:18,24 184:17 190:8 193:2,5 199:22 200:19 204:13 207:3,22,24 209:23 216:15 222:12 223:18 225:4,14 229:19	233:14 235:22 264:1 string 144:10 structures 161:11 studied 186:17 189:10 195:23 196:5 studies 206:11 222:22 232:4 253:14,24 254:13 258:2 study 168:7 200:7 200:12 201:2,10 202:16 206:3 232:10 265:15 subject 268:10 subscribed 270:15 substance 270:7 substantial 148:4 substitute 214:20 success 200:11,21 201:3 207:14 236:11,16,22 successful 236:19 successfully 192:24 226:2 sued 253:3 suffering 204:21 sufficient 155:15 254:9 suite 141:3,8,19 142:4 suits 211:2 supplemental 177:19 support 148:8,17 149:4,13,24 150:20 174:16 175:13 203:16,16 205:4 212:5 244:13 263:10 supports 174:10 supposed 211:16 supulveda 262:11 262:17 sure 158:16 163:15	164:5,8 166:21 174:21 176:20,21 187:23 188:3,7 210:6 215:21 216:24 217:9 218:5,18 221:9 228:5 230:13,14 231:16 234:15 surgeon 156:11 158:1 166:10 167:7,11,11,13,14 167:19 168:8 173:17,24 176:4 197:6 214:7 244:10 surgeons 158:13 162:7 168:18,21 169:5 176:24 177:5,8 257:11,15 258:19 261:4,14 261:16 262:5 surgeries 154:3 159:24 160:4,7,10 160:13,16,19,24 161:5,15,21 162:1 surgery 146:12 147:9 154:5,8,13 154:18 155:9,13 157:20 158:12 159:7,11,15,19 167:20 178:1,6 185:11,15 191:18 203:4 208:10 223:15 244:14 261:15 surgical 161:13,23 169:22 265:17 surprised 200:19 200:20 206:6 surrounding 161:7 198:9,15,19 202:6 203:20 survey 168:4,7 suture 233:11 sutures 146:5 147:7 183:5	sworn 145:3 267:4 270:15 system 138:3 256:12 <hr/> T <hr/> take 169:14 190:23 198:20 199:13 206:18 254:21 taken 140:6 191:3 226:12 254:23 267:7 targeted 246:24 taylor 139:20 141:15 team 186:12 248:18 250:10 technique 213:16 technologies 140:21 tell 169:16 218:21 237:23 telling 218:2 ten 146:4 tension 196:21 211:17 212:18 213:4,13,17,23 tensionfree 211:21 212:17 213:3 teri 139:19 term 187:2,18 197:11 198:2,3,6 terminology 187:8 terms 217:4,13 testified 145:4 165:8 169:10 220:10 259:16 testify 267:5 testimony 151:11 174:5 177:13 208:19 243:6 267:7 testing 187:11 texas 140:8,12 141:9,19 267:21 thank 146:14 163:2
--	--	--	--	--

thats 146:20 147:19 148:14 149:5,19 152:7,9,10 156:3 156:9,13 157:22 158:5 162:6 165:16 166:10,22 169:17 171:12 172:6,11 174:18 176:5 178:3 180:9 181:11 183:6,14 187:13 188:13,24 190:2 195:13,14 198:15 202:24 203:23 208:15,22 209:7 211:18 213:13 214:13 216:6,17 218:5 219:3 220:15 223:1 225:19 226:24 227:22 230:19 232:3 233:22 234:5 238:18 240:12 243:9 244:22 245:6,9 246:4 247:11 250:13,16 250:19,24 251:12 251:18,19 252:16 254:1,7 259:12 260:2,5,21 261:2 262:11 263:6 264:22 265:2 266:1,8 theoretically 164:6 164:8 therere 262:7 theres 148:2 153:3 167:1 177:21 179:22 180:12,16 180:19 182:7 196:19 203:24 206:13 211:7,7 214:14 222:21,22 223:15 240:23 241:8 258:16 260:12,17,22	265:12 theyre 148:11 156:15,16 162:13 166:11 170:1 184:11 186:8 190:15 203:15 209:5 221:21,22 233:5,6 234:15,16 258:23 thigh 161:18 thing 166:16 177:18 187:13 188:13 195:13 198:16 203:21 227:1 244:1 251:12,18,20 253:6,9 things 145:12 149:9 156:23 164:7,17 165:1 205:1 213:21 264:18 think 148:2 149:16 151:8 154:13,18 155:3,7 156:15,21 162:8 165:21 166:15,23 168:15 169:2,10 171:3 172:7,12 173:12 173:15,17,24 174:11,15 175:6 176:23 178:15 179:12,14 180:17 181:10,18 188:18 189:20 190:14,14 190:18,21 191:13 191:16 193:7,10 194:12,14 195:2 195:14,20 196:18 196:24 197:1 198:15 199:8 201:6,12 203:14 204:4 207:13 208:10 209:3,22 212:22 213:10,11 213:13 215:20 217:23 218:5,6,11	218:17,18,19 219:3,6,13,21 220:4,6,15 221:2 221:12,18 222:4 222:16,19,20 223:1 224:21 227:18 232:17 235:2 241:5 245:5 251:19 254:16 255:17 256:2 259:4 261:7 263:13,17 264:3,6 264:15 265:18 266:6 thinks 192:17,22 193:2 third 177:11 244:2 246:18 thirty 268:16 thought 156:23 164:14 182:15 193:14 194:16 211:20 212:1,4,9 223:4 249:23 three 170:13 172:8 172:8,13 202:17 202:24 258:14 259:4 thursday 140:2 time 146:6 147:15 147:18 150:23 160:22 165:10 172:16 199:10 208:3,6 220:12,19 232:19 239:8 248:21 249:11,17 249:18,24 253:19 254:9,14 263:18 267:8 timeline 247:2 times 190:8 tina 139:22 tissue 152:21 161:7 190:13,22 191:17 192:7 194:9,18 195:11,19 197:19	198:9,15,19 199:1 203:5,7,20 204:6 213:11,22 224:24 230:1,18 235:12 244:16 tissues 189:18 202:5 226:4 227:5 227:14,21 233:20 236:3 titled 246:15 today 149:10,17 162:11 178:1,6,10 185:23 202:20 209:11 242:12,20 256:5 257:5 258:7 261:23 told 171:9 193:22 223:5 230:21 234:7 235:8 top 179:12 202:14 230:21 262:12 total 238:1,2 traditional 226:20 227:9,13 train 263:20 trained 213:15 training 145:24 176:8 177:7 transcript 267:7 268:17,18 transcription 270:5 translate 224:1 transvaginal 169:12 171:4,6 173:6 204:19 209:3 218:16,24 219:10 transvaginally 173:18 174:2 178:1,6,10 treated 204:21 240:4 treatment 161:23 169:23 183:1 184:4 213:9 222:4 226:2,7 227:9	228:16 246:2 248:24 249:14,21 250:18 trial 238:24 243:10 trials 229:14,22 230:15 tried 182:14 260:4 trim 258:20 trimming 232:19 trocars 186:10 true 147:23 152:6 152:20,24 172:6 172:11 203:23 263:6 truth 267:5,5,5 try 146:16 176:11 trying 154:16 223:22 229:2 turn 246:16 247:23 tvm 205:4 tv 182:2 214:8 237:13 twohour 254:17 type 188:10,21 189:1 192:18 typical 146:16 165:9 168:8 175:18,21 176:14 176:23 typically 165:13 <hr/> U <hr/> u 138:5 uhhuh 243:1 ultimately 245:24 ultrasonically 232:1,7,11 umbilical 145:24 146:8,10,17 unaware 259:17 understand 154:17 157:6 176:20,21 185:22 191:21 230:11 understanding 244:19,22
--	---	---	--	--

understood 211:21 212:5,12,18 213:3 unfortunately 207:16 unfounded 211:3,4 211:13 234:13 235:14 236:5 unique 155:5 204:10 united 138:1 164:4 168:8 178:2,10 210:22 211:10 unnecessary 156:4 156:8,16 157:20 158:4 162:4 164:18 165:2 unreasonable 166:22 unsafe 251:11,18 unsupported 152:4 update 165:19 168:14,24 169:9 173:19 updated 166:8 169:15 urethra 161:12 urge 159:16 urinary 159:12,20 159:20 192:19 urology 144:12 247:20 250:4 use 147:10 152:22 154:9 168:14 169:1,8,15 170:12 170:20,23 172:15 174:16 175:22,23 176:2,3,15,16,18 176:19,19,22 177:1,2,14,15,17 178:2,12 184:23 189:2 218:15 219:10,18 220:2 227:5,13 230:22 256:11,14 257:24 263:10,16,19 264:9 265:13,21	user 165:23 184:7 users 262:5,8 uses 215:10,18 244:24 245:12 usually 258:21 uterine 169:22 uterosacral 204:9 utilized 192:23 <hr/> V vagina 189:22 223:16 vaginal 152:23,23 154:9,19 169:22 203:17 212:5 226:4 227:5,13,21 228:2,8 233:20 235:12 236:3 244:15 vaguely 248:7 variable 160:21 verbatim 267:7 vessels 161:11 virginia 138:1,15 voiding 160:1,21 voluminous 260:3 <hr/> W wagstaff 141:2 wake 213:20 wall 145:18 203:17 244:15 want 145:14 162:24 169:14 173:19 174:6 175:2,7 179:4,16 190:23 203:6 217:20 219:7 220:3,16 223:3,9 263:19 warlick 139:10 warn 152:2 155:2 211:6,8 warned 217:3,11 warning 151:7 warnings 150:6 151:20 256:6,11	warns 198:8 warranted 169:24 wasnt 147:17 163:21 239:23 254:9 waugh 141:19 wave 138:6 144:9 way 156:9 165:17 168:23 184:15 186:5 213:21 215:16 247:9 258:17 266:7 wcllp 141:3 website 250:6,11 websites 250:7,12 weight 183:10 245:1,6,14,20 wendy 139:2 went 240:8,15 west 138:1 westin 140:7 weve 198:18 218:3 218:14 whats 162:21 176:5 243:15 246:10 247:16 white 138:15 whos 263:13 264:6 widely 192:23 william 142:2,3 163:1 178:24 254:15 255:4 williams 139:16 wilson 138:23 withdraw 229:20 witness 169:19 179:11 243:17 267:10,11 268:1 wolfe 138:17 178:19 woman 217:5,14 womans 182:24 226:4 233:20 236:3 women 152:22 204:20 209:5,20	210:2,11 womens 144:12 250:3 word 158:21 167:24 183:18 work 259:23 263:1 worked 185:20 186:10,11 working 239:21 259:1 works 194:14 195:5 wouldnt 147:16 156:15 157:21 165:13 166:9,22 174:6 180:3 212:21 220:22 229:2 240:9 263:8 265:6 wound 160:8 183:16 234:21 wrinkling 244:11 wrong 148:5 234:12 wrongful 147:24 148:3,9,19 149:2 149:15 221:2,13 222:5 <hr/> X <hr/> Y yeah 148:2 163:2 174:14 179:18 188:17 196:4,24 239:23 242:2 254:20 265:9 year 239:18 years 146:1,4 147:1 170:13,17 172:8,8 172:13 239:14 259:4 yesterday 155:20 155:23 169:10 255:6 256:20,24 257:5 258:7 youd 230:12 251:21	260:11,17 youll 198:1,2 youre 146:8 165:23 174:9 176:3 182:1 183:7 186:14 191:22 195:17 204:5 230:5 241:9 264:12 youve 166:3 188:4 202:3 210:18 220:10,11 237:9 241:5,12,14 242:6 242:9,13 243:3 259:6 264:3 <hr/> Z zero 201:2 zipfel 243:20,20 zoomerang 144:16 <hr/> 0 00 226:12 000 211:9 01 144:14 02 144:11 03 144:10,10 06 266:13 09 191:3 226:13 <hr/> 1 1 138:6 144:9 180:18 189:16,21 190:20 191:15 194:8,13,14,17 10 226:12,13 254:23,24 100 141:8,19 200:18,21 1020 142:3 11 144:5 155:21,24 256:6 266:13 12 144:6 162:19,22 12cv00276 139:10 12cv00277 138:7 12cv00335 138:17 12cv00368 139:6 12cv00376 139:21
--	---	---	--	---

Christina Pramudji, M.D.

Page 289

12cv00378 139:22 12cv00379 139:19 12cv00401 139:24 12cv00470 138:14 12cv00483 139:9 12cv00511 139:16 12cv00547 138:11 12cv00554 138:13 12cv00651 139:7 12cv00652 139:18 12cv00760 138:22 12cv00783 139:3 12cv00799 139:4 12cv00806 138:8 12cv00878 138:20 12cv00899 139:1 12cv00938 138:10 12cv00958 138:16 12cv00960 139:12 12cv01119 139:15 12cv01275 139:13 12cv01286 138:23 12cv01318 138:19 12md02327 138:3 13 140:9 144:7,14 181:22 182:5 13th 247:19 14 144:10 243:12 243:15 1400 142:4 142 143:4 145 143:7 15 144:11 246:7,10 155 144:5 16 144:14 191:4 247:13,17,18 162 144:6 17 144:16 202:17 202:23 203:5,8,11 247:14,17 181 144:7 1996 147:10,13,17 1997 147:10 1998 192:10 1millimeter 189:7 195:24 196:6	<hr/> 2 <hr/> 2 138:3,7,8,10,11 138:13,14,16,17 138:19,20,22,23 139:1,3,4,6,7,9,10 139:12,13,15,16 139:18,19,21,22 139:24 200:1 205:21 20 270:16 200 138:6 2005 193:16 224:5 240:1 2008 144:11 209:16 246:15 249:3 251:7 254:14 2009 144:10,10,14 229:6 247:19 248:6,22 249:12 249:19 250:22,23 253:19 2011 209:16 2012 208:10,12,16 250:15 2013 170:8,22 173:19,22 218:12 265:22 2015 162:16 163:7 163:8 164:12 166:8 167:9,16 169:16 170:7 217:21 2016 138:10 140:2 143:2 144:2 267:21,22 214 141:9 24 138:10 140:2 143:2 144:2 267:22 243 144:10 246 144:11 247 144:14,16 255 143:8 264 143:9 267 143:11 27 144:11	270 143:13 271 143:14 276 143:12 27th 246:15 29 144:10 <hr/> 3 <hr/> 30 144:10 242:15 242:23 267:10 268:16 300 141:3 3031 141:8 3377 140:21 350 141:19 370 140:21 39157 142:4 3rd 163:8 <hr/> 4 <hr/> 41 254:23 4740 141:3 <hr/> 5 <hr/> 50 242:16,24 504 141:14 513 206:16 522 171:11,16 53 254:24 5505239 141:9 5672 140:21 5814892 141:14 591 140:21 <hr/> 6 <hr/> 600 243:3 601 142:5 64112 141:4 <hr/> 7 <hr/> 70 211:9 700 243:7 7011100 141:4 70113 141:14 713 141:20 75 191:20 194:23 195:12 75204 141:9	77007 141:19 <hr/> 8 <hr/> 8 140:9 267:21,21 816 141:4 820 141:13 877 140:21 <hr/> 9 <hr/> 9 191:3,4 917 140:21 945 140:8 9485711 142:5 9638881 141:20
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Christina Pramudji, M.D.

Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.,)MASTER FILE NO.
PELVIC REPAIR SYSTEM)2:12-MD-02327
PRODUCTS LIABILITY)
LITIGATION)
)MDL 2327
-----)
)
Joy Essman)IN RE TVT & TVT-O
Case No. 2:12-cv-00277)
)
Barbara A. Hill)JOSEPH R. GOODWIN
Case No. 2:12-cv-00806)U.S. DISTRICT JUDGE
)
Paula Kriz)
Case No. 2:12-cv-00938)DEPOSITION OF
)CHRISTINA PRAMUDJI, M.D.
Brenda Riddell)
Case No. 2:12-cv-00547)
)
Sharon Carpenter)
Case No. 2:12-cv-00554)
)
Mary Jane Olsen)
Case No. 2:12-cv-00470)
)MARCH 24, 2016
Virginia White)
Case No. 2:12-cv-00958)
)
Sandra Wolfe)
Case No. 2:12-cv-00335)
)
Marie Smith (f/k/a Banks))
Case No. 2:12-cv-01318)
)
Sherry Fox)
Case No. 2:12-cv-00878)
)
Lois Durham)
Case No. 2:12-cv-00760)
)
Elizabeth Blynn Wilson)
Case No. 2:12-cv-01286)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 2</p> <p>1 Daphne Baker) Case No. 2:12-cv-00899) 2) Wendy Hagans) 3 Case No. 2:12-cv-00783) 4) Maria Eugenia Quijano) Case No. 2:12-cv-00799) 5) Sharon Boggs) 6 Case No. 2:12-cv-00368) 7) Robin Bridges) Case No. 2:12-cv-00651) 8) Carey Cole) Case No. 2:12-cv-00483) 9) Cathy Warlick) Case No. 2:12-cv-00276) 10) Donna Amsden) Case No. 2:12-cv-00960) 11) Heather Long) Case No. 2:12-cv-01275) 12) Penny Rhynehart) Case No. 2:12-cv-01119) 13) Nancy Jo Williams) Case No. 2:12-cv-00511) 14) Maria Stone) Case No. 2:12-cv-00652) 15) Teri Key Shively) Case No. 2:12-cv-00379) 16) Charlene Logan Taylor) Case No. 2:12-cv-00376) 17) Tina Morrow) Case No. 2:12-cv-00378) 18) Carol Jean Dimock) Case No. 2:12-cv-00401) 19) 20) 21) 22) 23) 24)</p>	<p style="text-align: right;">Page 4</p> <p>1 APPEARANCES: 2 WAGSTAFF & CARTMELL, LLP BY: ANDREW N. FAES, ESQUIRE 3 afaes@wcllp.com 4 4740 Grand Avenue, Suite 300 Kansas City, Missouri 64112 (816) 701-1100 5 Counsel for Plaintiffs 6 EDWARDS & DE LA CERDA, P.L.L.C. 7 BY: PETER DE LA CERDA, ESQUIRE peter@edwardsdelacerda.com 8 (Via Speakerphone) 3031 Allen Street, Suite 100 9 Dallas, Texas 75204 (214) 550-5239 10 Counsel for Amsden Plaintiff 11 HERMAN, HERMAN & KATZ, LLC 12 BY: MIKALIA M. KOTT, ESQUIRE mkott@hklawfirm.com 13 (Via Speakerphone) 820 O'Keefe Avenue 14 New Orleans, Louisiana 70113 (504) 581-4892 15 Counsel for Taylor and Shively Plaintiffs 16 THE POTTS LAW FIRM, LLP 17 BY: STEPHEN R. RICKS, ESQUIRE sricks@potts-law.com 18 (Via Speakerphone) 19 100 Waugh Drive, Suite 350 Houston, Texas 77007 20 (713) 963-8881 Counsel for Carpenter Plaintiff 21 22 23 24</p>
<p style="text-align: right;">Page 3</p> <p>1 2 - - - 3 4 Thursday, March 24, 2016 5 6 - - - 7 8 Oral Deposition of CHRISTINA 9 PRAMUDJI, M.D., In Re TVT and TVT-O, taken 10 pursuant to notice, was held at the Westin 11 Houston, Memorial City, 945 Gessner Road, 12 Houston, Texas, beginning at 11:10 a.m., on 13 the above date, before Micheal A. Johnson, 14 Registered Diplomate Reporter, Certified 15 Realtime Reporter, and Notary Public for the 16 State of Texas. 17 18 - - - 19 20 21 22 23 24</p>	<p style="text-align: right;">Page 5</p> <p>1 APPEARANCES: 2 BUTLER SNOW LLP BY: WILLIAM M. GAGE, ESQUIRE 3 william.gage@butlersnow.com 4 1020 Highland Colony Parkway Suite 1400 5 Ridgeland, Mississippi 39157 (601) 948-5711 6 Counsel for Defendants 7 8 - - - 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>

Christina Pramudji, M.D.

Page 6				Page 8			
1	INDEX			1	PROCEEDINGS		
2	CHRISTINA PRAMUDJI, M.D.			2	CHRISTINA PRAMUDJI, M.D.,		
3	March 24, 2016			3	having been first duly sworn,		
4	APPEARANCES	4		4	testified as follows:		
5				5	EXAMINATION		
6	EXAMINATION OF CHRISTINA PRAMUDJI, M.D.:			6	BY MR. FAES:		
7	BY MR. FAES	8		7	Q. Doctor, my name is Andy Faes,		
8	BY MR. GAGE	66		8	and I'm here to take your deposition now		
9	BY MR. FAES	68		9	regarding the TVT and TVT-O case. Do you		
10				10	understand that?		
11	CERTIFICATE	69		11	A. Yes.		
12	ERRATA	71		12	Q. You understand that you're		
13	ACKNOWLEDGMENT OF DEPONENT		72	13	still under oath from earlier and you're		
14	LAWYER'S NOTES	73		14	still sworn to tell the truth, correct?		
15				15	A. Yes.		
16				16	Q. And again, as before, if I ask		
17				17	a question that doesn't make sense to you,		
18				18	please let me know and I'll try to rephrase		
19				19	the question.		
20				20	A. Okay.		
21				21	MR. FAES: I'm just going to		
22				22	continue the exhibit numbers. Is that		
23				23	okay?		
24				24	MR. GAGE: That's fine.		
Page 7				Page 9			
1	DEPOSITION EXHIBITS			1	(Deposition Exhibit 18 marked.)		
2	CHRISTINA PRAMUDJI, M.D.			2	BY MR. FAES:		
3	March 24, 2016			3	Q. Doctor, I'm going to hand you		
4	NUMBER DESCRIPTION MARKED			4	what's been marked as Exhibit No. 18 to your		
5	Exhibit 18 Expert Report of	9		5	deposition. Can you tell me what that is?		
6	Christina Pramudji, M.D.			6	MR. GAGE: And just for the		
7	Exhibit 19 CV of Christina Klein	14		7	record, when he says, "We're		
8	Pramudji			8	continuing the exhibit numbers," he		
9	Exhibit 20 04/21/2014 E-mail String	34		9	means we're continuing the exhibit		
10	Exhibit 21 Gynecare TVT	43		10	numbers that were marked from		
11	Tension-free Vaginal			11	Dr. Pramudji's prior deposition that		
12	Tape System -			12	was this morning and then yesterday in		
13	Instructions For Use			13	the Prolift, Prosima and Gynemesh PS		
14	PREVIOUSLY MARKED EXHIBITS			14	cases.		
15	NUMBER DESCRIPTION REFERENCED			15	MR. FAES: Right. And we		
16	Exhibit 13 10			16	may -- actually, we are going to refer		
17				17	back to some of those exhibits as		
18				18	well.		
19				19	A. This is my expert report		
20				20	containing my opinions about the TVT.		
21				21	BY MR. FAES:		
22				22	Q. Does this report contain each		
23				23	of the opinions you've reached regarding the		
24				24	TVT and TVT-O?		

3 (Pages 6 to 9)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 10</p> <p>1 A. Yes, thus far.</p> <p>2 Q. Now, this report discussed</p> <p>3 various facts. Did you discuss the facts in</p> <p>4 your report that you felt were the most</p> <p>5 important to you in drawing your opinions in</p> <p>6 this report?</p> <p>7 A. Yes.</p> <p>8 Q. And there are articles cited</p> <p>9 here in your report. And in terms of your</p> <p>10 decision-making and writing the report, why</p> <p>11 did you cite to those articles in your</p> <p>12 report?</p> <p>13 A. I felt like those articles had</p> <p>14 the best level I data, as far as randomized</p> <p>15 control trials, and reviews which were the</p> <p>16 most rigorous.</p> <p>17 BY MR. FAES:</p> <p>18 Q. And you've also got a reliance</p> <p>19 list which is in front of you, which is</p> <p>20 previously marked as Exhibit 13 in your</p> <p>21 previous deposition. Is that all -- is that</p> <p>22 a list of all the material that you've</p> <p>23 reviewed and relied upon for your TVT and</p> <p>24 TVT-O opinions in addition to the materials</p>	<p style="text-align: right;">Page 12</p> <p>1 estimate that you spent?</p> <p>2 A. Maybe ten hours.</p> <p>3 Q. And what previous report did</p> <p>4 you modify to create the report that's in</p> <p>5 front of you?</p> <p>6 A. I had done a TVT report in a</p> <p>7 previous case, I think it was -- was it --</p> <p>8 Bellew, if I remember correctly.</p> <p>9 Q. I don't think it was Bellew.</p> <p>10 A. No. Oh, Huskey. Huskey.</p> <p>11 Q. Okay. And that report was</p> <p>12 issued in 2014; is that correct?</p> <p>13 A. That sounds about right.</p> <p>14 Q. So you hadn't updated your TVT</p> <p>15 or TVT-O opinions between 2014 and when this</p> <p>16 report was signed in February of this year?</p> <p>17 A. I believe that's correct.</p> <p>18 Q. Do you recall specifically any</p> <p>19 new opinions that you have that are contained</p> <p>20 within this report that are important to you</p> <p>21 that have changed since the last time you</p> <p>22 were deposed in 2014 and testified?</p> <p>23 A. No.</p> <p>24 Q. Doctor, I've added up the</p>
<p style="text-align: right;">Page 11</p> <p>1 cited in your report?</p> <p>2 A. Yes, I believe so.</p> <p>3 Q. Are there any materials that</p> <p>4 you reviewed or relied upon in forming your</p> <p>5 opinions that are not either listed in your</p> <p>6 report marked as Exhibit 18 or in your</p> <p>7 reliance list marked as Exhibit 13?</p> <p>8 A. Not that I can think of right</p> <p>9 now.</p> <p>10 Q. Can you tell me when you were</p> <p>11 first contacted about being an expert for</p> <p>12 this case, meaning this particular report? I</p> <p>13 know you've served as an expert for TVT and</p> <p>14 TVT-O in the past, but when were you first</p> <p>15 contacted to be an expert for this particular</p> <p>16 wave?</p> <p>17 A. I believe it was in November of</p> <p>18 2015.</p> <p>19 Q. And how many hours would you</p> <p>20 say you've spent completing your general</p> <p>21 report?</p> <p>22 A. Well, I just had to modify a</p> <p>23 previous report, so it wasn't that much time.</p> <p>24 Q. And how many hours would you</p>	<p style="text-align: right;">Page 13</p> <p>1 number of hours that you estimate you've</p> <p>2 worked for these Wave 1 cases. You told me</p> <p>3 that you estimated between 30 and 50 hours</p> <p>4 for each case-specific report, which would</p> <p>5 put you between 420 and 700 hours. Do you</p> <p>6 have any reason to disagree with my math on</p> <p>7 that?</p> <p>8 A. No, that sounds right.</p> <p>9 Q. And those hours would be billed</p> <p>10 at \$600 an hour, correct?</p> <p>11 A. Correct.</p> <p>12 Q. So if you multiply those</p> <p>13 numbers, I estimate that you will be paid</p> <p>14 approximately between 252,000 and \$420,000</p> <p>15 just for your case-specific opinions in this</p> <p>16 Wave 1; is that correct?</p> <p>17 A. That sounds like correct math.</p> <p>18 Q. And in addition, you'll bill</p> <p>19 approximately \$36,000 for your TVT-O general</p> <p>20 report and your Prosima Gynemesh PS and</p> <p>21 Prolift report, based on 50 hours for the</p> <p>22 Prosima, Prolift, Gynemesh PS report and</p> <p>23 ten hours for the TVT report. Does that</p> <p>24 sound correct?</p>

4 (Pages 10 to 13)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 14</p> <p>1 A. Yes.</p> <p>2 Q. So in total, if my math is</p> <p>3 correct, you stand to be paid by Ethicon's</p> <p>4 attorneys somewhere between 288,000 and</p> <p>5 \$456,000 for the reports you've issued in</p> <p>6 this Wave 1?</p> <p>7 A. Yes.</p> <p>8 Q. Doctor, you've provided a CV</p> <p>9 with your report; is that correct?</p> <p>10 A. Yes.</p> <p>11 Q. I'll make another copy of your</p> <p>12 CV as 19. It's one that was with the report,</p> <p>13 but I don't think that's going to materially</p> <p>14 affect the questions I'm going to ask.</p> <p>15 (Deposition Exhibit 19 marked.)</p> <p>16 BY MR. FAES:</p> <p>17 Q. Doctor, within your CV is a</p> <p>18 list of publications. Do any of the</p> <p>19 publications in your CV specifically address</p> <p>20 the TVT or TVT-O?</p> <p>21 A. No.</p> <p>22 Q. You've never published in the</p> <p>23 area of sling complications; is that right?</p> <p>24 A. That's correct.</p>	<p style="text-align: right;">Page 16</p> <p>1 of the sling or the mechanically cut version</p> <p>2 of the sling?</p> <p>3 A. I don't know.</p> <p>4 Q. Do you know how to tell the</p> <p>5 difference if you were to pick up the box?</p> <p>6 A. I believe that the -- no, I</p> <p>7 really don't.</p> <p>8 Q. And you do know that both the</p> <p>9 TVT Exact and the TVT Abbrevio products are</p> <p>10 only offered in laser cut mesh, right?</p> <p>11 A. I don't really know. I don't</p> <p>12 really pay attention.</p> <p>13 Q. You don't know?</p> <p>14 A. It doesn't matter clinically.</p> <p>15 Q. Do you -- are you currently</p> <p>16 still using the Solyx device?</p> <p>17 A. No.</p> <p>18 Q. Did you ever end up enrolling</p> <p>19 any patients for the Solyx clinical trial?</p> <p>20 A. No. I moved practices in</p> <p>21 the -- midstream of setting up that trial,</p> <p>22 and it was just too cumbersome to try to set</p> <p>23 it up and start my own business at the same</p> <p>24 time.</p>
<p style="text-align: right;">Page 15</p> <p>1 Q. Do any of your publications</p> <p>2 specifically address midurethral</p> <p>3 polypropylene slings?</p> <p>4 A. No.</p> <p>5 Q. I realize you've been asked</p> <p>6 this, but it's been a couple of years.</p> <p>7 Doctor, what slings do you currently use?</p> <p>8 A. Currently use the TVT Exact,</p> <p>9 TVT Obturator and TVT Abbrevio.</p> <p>10 Q. Have you done preceptorships</p> <p>11 for all three of those products?</p> <p>12 A. I have not done preceptorships</p> <p>13 for TVT Exact and retropubic TVT, but I did</p> <p>14 do preceptorships for Obturator and Abbrevio.</p> <p>15 Q. That's what I thought you were</p> <p>16 going to say. So you no longer, at least</p> <p>17 currently, use the TVT retropubic or classic</p> <p>18 TVT product; you only use the TVT Exact,</p> <p>19 which I understand is also a retropubic</p> <p>20 sling, but it's not the original 1998</p> <p>21 version, correct?</p> <p>22 A. Correct.</p> <p>23 Q. When you use the TVT-O sling,</p> <p>24 do you know if you use the laser cut version</p>	<p style="text-align: right;">Page 17</p> <p>1 Q. Have you implanted any Solyx</p> <p>2 devices in the last three years?</p> <p>3 A. No, I don't believe so.</p> <p>4 Q. Have you implanted any products</p> <p>5 other than -- strike that.</p> <p>6 Have you implanted any</p> <p>7 midurethral polypropylene slings other than</p> <p>8 the TVT Exact, TVT-O and TVT Abbrevio in the</p> <p>9 last three years?</p> <p>10 A. I think I tried the Mini-Arc</p> <p>11 once or twice.</p> <p>12 Q. So it's --</p> <p>13 A. But that's all I can remember.</p> <p>14 Q. What would you say is your</p> <p>15 sling of choice right now?</p> <p>16 A. In my hands, I really like the</p> <p>17 TVT Exact.</p> <p>18 Q. What percentage of the time</p> <p>19 would you say you implant that device as</p> <p>20 compared to the other slings?</p> <p>21 A. Probably 95 percent of the</p> <p>22 time.</p> <p>23 Q. And what patients -- what types</p> <p>24 of patients do you choose to perform the</p>

5 (Pages 14 to 17)

Christina Pramudji, M.D.

Page 18	Page 20
<p>1 TVT-O or TVT Abbrevio procedure?</p> <p>2 A. I tend to use those more for</p> <p>3 patients with occult stress incontinence when</p> <p>4 I'm doing a prolapse repair, or if they have</p> <p>5 any sign of a weak bladder or poor emptying,</p> <p>6 I might be more inclined to do those slings</p> <p>7 rather than the retropubic.</p> <p>8 Q. Okay. Has Ethicon ever asked</p> <p>9 you to offer your opinions on the TVT-Secur</p> <p>10 sling as an expert?</p> <p>11 A. No.</p> <p>12 Q. What about the Abbrevio?</p> <p>13 A. No.</p> <p>14 Q. Or the Exact, TVT Exact?</p> <p>15 A. I don't think so.</p> <p>16 Q. What other surgical procedures</p> <p>17 do you currently perform for the treatment of</p> <p>18 stress urinary incontinence other than the</p> <p>19 three products you mentioned?</p> <p>20 A. I also do autologous fascial</p> <p>21 slings. I do biological midurethral -- I</p> <p>22 should say biological retropubic slings with</p> <p>23 a biological graft and Coaptite periurethral</p> <p>24 bulking.</p>	<p>1 Scientific products.</p> <p>2 Q. Are you still a consultant for</p> <p>3 Boston Scientific?</p> <p>4 A. No.</p> <p>5 Q. When did that relationship end?</p> <p>6 A. I think it's been a couple of</p> <p>7 years since I did anything with them. A year</p> <p>8 or two. I can't recall.</p> <p>9 Q. Are there any other mesh</p> <p>10 companies that you are currently doing</p> <p>11 consulting work for?</p> <p>12 A. No.</p> <p>13 Q. Are there any other medical</p> <p>14 device companies that you are currently doing</p> <p>15 consulting work for?</p> <p>16 A. Not right now.</p> <p>17 Q. Are there any other</p> <p>18 pharmaceutical companies that you're</p> <p>19 currently doing any consulting work for?</p> <p>20 A. No, not right now.</p> <p>21 Q. Would it be fair to say that</p> <p>22 you've been pretty loyal to Ethicon's stress</p> <p>23 urinary incontinence products in terms of</p> <p>24 polypropylene slings for the last</p>
Page 19	Page 21
<p>1 Q. Is that a surgical procedure?</p> <p>2 A. Yes.</p> <p>3 Q. Would you say that your use of</p> <p>4 autologous fascial slings and biological</p> <p>5 slings has increased in the last few years?</p> <p>6 A. No, it's stable.</p> <p>7 Q. What biological slings do you</p> <p>8 currently use?</p> <p>9 A. I usually -- there's no, you</p> <p>10 know, kit or marketed product for that, so I</p> <p>11 usually fashion it out of Xenform,</p> <p>12 X-e-n-f-o-r-m, material.</p> <p>13 Q. That's a Boston Scientific</p> <p>14 product, right?</p> <p>15 A. Yes.</p> <p>16 Q. Do you know if you're currently</p> <p>17 using any other Boston Scientific products</p> <p>18 other than Xenform, except for potentially</p> <p>19 you may be using the Uphold product in the</p> <p>20 future as you mentioned earlier?</p> <p>21 A. They have a vaginal manipulator</p> <p>22 that I use during sacrocolpopexy. That's the</p> <p>23 only thing for pelvic floor. Then I use some</p> <p>24 things for kidney stones that are Boston</p>	<p>1 three years?</p> <p>2 A. Yes.</p> <p>3 Q. In your report on page 7, you</p> <p>4 state that you've reviewed the expert reports</p> <p>5 submitted by plaintiffs, specifically</p> <p>6 Drs. Rosenzweig, Margolis and Carey. Is that</p> <p>7 correct?</p> <p>8 A. Yes.</p> <p>9 Q. Do you recall, have you</p> <p>10 reviewed any other expert reports in this</p> <p>11 wave?</p> <p>12 A. Regarding TVT?</p> <p>13 Q. Yes.</p> <p>14 A. Not that I can recall right</p> <p>15 now.</p> <p>16 Q. You also state that you</p> <p>17 reviewed the materials cited in the reports</p> <p>18 and their expert depositions; is that</p> <p>19 correct?</p> <p>20 A. Yes.</p> <p>21 Q. Did you review every single</p> <p>22 document that they cited in their reports?</p> <p>23 A. For the most part.</p> <p>24 Q. Who got those documents for</p>

6 (Pages 18 to 21)

Christina Pramudji, M.D.

Page 22	Page 24
<p>1 you?</p> <p>2 A. Butler Snow helped me to gather</p> <p>3 them together.</p> <p>4 Q. Is there any particular</p> <p>5 reason -- actually -- yeah. Is there any</p> <p>6 particular reason why you chose to review the</p> <p>7 expert reports of just those three</p> <p>8 individuals?</p> <p>9 A. I can't remember if I reviewed</p> <p>10 others, but I just have reviewed everything</p> <p>11 that I could.</p> <p>12 Q. If you've reviewed others, how</p> <p>13 would I determine that? Are those listed on</p> <p>14 your reliance list or anywhere else?</p> <p>15 A. Trying to remember.</p> <p>16 MR. FAES: I mean, here's the</p> <p>17 problem, William, is I don't even see</p> <p>18 these three listed on her reliance</p> <p>19 list and there's only three listed in</p> <p>20 her report. So if there's other ones</p> <p>21 she's reviewed, I need to know that.</p> <p>22 MR. GAGE: All right.</p> <p>23 BY MR. FAES:</p> <p>24 Q. Okay. Is the answer you don't</p>	<p>1 Ultrapro is because Ethicon has chosen not to</p> <p>2 market that device, correct?</p> <p>3 A. I don't know the details behind</p> <p>4 that.</p> <p>5 Q. Do you know what the TVT-O PA</p> <p>6 is?</p> <p>7 A. No.</p> <p>8 Q. So I take it, then, that you</p> <p>9 don't know whether or not the TVT-O PA was an</p> <p>10 obturator sling developed by Ethicon that had</p> <p>11 the Ultrapro mesh rather than the mesh that's</p> <p>12 currently used in the TVT-O?</p> <p>13 A. No, I'm not familiar with that.</p> <p>14 Q. Do you know whether or not</p> <p>15 Ethicon stated to the FDA that the TVT-O PA</p> <p>16 with the Ultrapro material was substantially</p> <p>17 equivalent to the TVT-O?</p> <p>18 MR. GAGE: Object to form.</p> <p>19 A. I'm not familiar with that.</p> <p>20 BY MR. FAES:</p> <p>21 Q. Is that something that would</p> <p>22 change your opinion on whether or not there</p> <p>23 is clinical data on the use of the Ultrapro</p> <p>24 mesh as it relates to SUI patients if the</p>
Page 23	Page 25
<p>1 recall at this time?</p> <p>2 A. Yeah, I can't recall right now.</p> <p>3 Q. We'll just move on. On page 18</p> <p>4 of your report, you state that you "know of</p> <p>5 no pelvic floor surgeons in the state of</p> <p>6 Texas or in the United States who use PVDF or</p> <p>7 kits employing PVDF to treat SUI or mixed</p> <p>8 UI" -- mixed urinary incontinence -- "the</p> <p>9 same can be true for Vypro and Ultrapro</p> <p>10 mesh."</p> <p>11 Is that correct?</p> <p>12 A. That's correct.</p> <p>13 Q. You know that the Ultrapro mesh</p> <p>14 is not available from Ethicon in a</p> <p>15 preconfigured sling like the TVT and the</p> <p>16 TVT-O, correct?</p> <p>17 A. Correct.</p> <p>18 Q. So if a physician were to want</p> <p>19 to use the Ultrapro in a sling, they would</p> <p>20 essentially have to fashion the sling</p> <p>21 themselves out of Ultrapro flat mesh, right?</p> <p>22 A. Correct.</p> <p>23 Q. And the reason that it's not</p> <p>24 available in a preconfigured sling with</p>	<p>1 manufacturer of the ULTRAPRO mesh told the</p> <p>2 FDA that it was substantially equivalent to</p> <p>3 the TVT-O already on the market?</p> <p>4 MR. GAGE: Object to form.</p> <p>5 A. I don't know.</p> <p>6 BY MR. FAES:</p> <p>7 Q. You state on page 19 of your</p> <p>8 report that the "Vypro and the Ultrapro also</p> <p>9 have a partially absorbable component and the</p> <p>10 data do not show that these meshes would work</p> <p>11 in the TVT design as the mesh sticks to the</p> <p>12 sheath and tears apart on sheath removal,</p> <p>13 losing integrity."</p> <p>14 Is that correct?</p> <p>15 A. That's correct.</p> <p>16 Q. How do you know that the</p> <p>17 Ultrapro would stick to the sheath and tear</p> <p>18 apart during sheath removal?</p> <p>19 A. From the data.</p> <p>20 Q. What data?</p> <p>21 A. I'm trying to remember where I</p> <p>22 got this from. I would have to look through</p> <p>23 to remember where I got this from.</p> <p>24 Q. Do you know whether or not</p>

7 (Pages 22 to 25)

Christina Pramudji, M.D.

Page 26	Page 28
<p>1 Ethicon engineers worked on the problem of 2 the Ultrapro mesh sticking to the sheaths 3 during the sheath removal and ultimately 4 solved that problem? 5 MR. GAGE: Object to form. 6 A. I can't recall right now. 7 BY MR. FAES: 8 Q. If that were indeed the case 9 and Ethicon engineers had solved that 10 problem, is that something that could 11 potentially change your opinion, that the 12 Ultrapro mesh would stick to the sheath and 13 tear apart upon sheath removal, losing 14 integrity? 15 A. Sure. 16 Q. You state on page 21 of your 17 report that pain and dyspareunia can occur 18 with all surgeries, as can organ damage and 19 bladder perforation. And on the following 20 page -- is that correct, first of all? 21 A. Yes, that's correct. 22 Q. On the following page you say, 23 "Moreover these risks are obvious to pelvic 24 floor surgeons performing SUI surgeries,"</p>	<p>1 be no clinically significant effect; is that 2 correct? 3 A. Absolutely. 4 Q. So it's your opinion that a 5 particle of Prolene that's directly under the 6 skin of the vagina couldn't cause pain or 7 discomfort for the patient? 8 A. That's correct. 9 Q. Even in the vagina, where 10 there's friction, if there were friction -- 11 if there were a piece of Prolene directly 12 underneath the skin in the vagina and you 13 know in the vagina there's friction that 14 occurs during intercourse, you don't believe 15 that that could cause discomfort or pain 16 under any circumstance? 17 MR. GAGE: Object to form. 18 A. No. What I would clarify is 19 that, yes, any Prolene suture, mesh, 20 particles, if they're too superficial, then, 21 yeah, that could cause discomfort. We see 22 sutures that are used in prolapse repairs 23 that will be right under the surface and that 24 can cause friction and irritation.</p>
Page 27	Page 29
<p>1 giving their described surgical techniques 2 and instruments and materials used during SUI 3 surgery. 4 Is that correct? 5 A. Yes. 6 Q. Do you know whether pain and 7 dyspareunia, organ damage and bladder 8 perforation are warned about in the IFU? 9 A. I would have to review it to 10 say definitively. 11 Q. Well, I'll represent to you 12 that, at least as of 2015, all of those risks 13 are now in the IFU. So assuming that to be 14 true, if they are obvious, do you have an 15 opinion as to why Ethicon chose to include 16 them in their IFU anyway as of 2015? 17 MR. GAGE: Object to form. 18 A. I'm not sure why they put them 19 in. I don't have a problem with it. I don't 20 think it's necessary, but it's reasonable. 21 BY MR. FAES: 22 Q. You state on page 28 of your 23 report that even if particles from the TVT 24 mesh were to get into the vagina, there would</p>	<p>1 BY MR. FAES: 2 Q. So you would agree that if a 3 particle from a TVT became loose and became 4 too superficial in the vagina, it could cause 5 discomfort or pain, particularly during 6 friction from intercourse? 7 A. If it were too superficial and 8 there was some irritation around it, it's 9 potential. But the particle issue is really 10 not an issue. It's really not something that 11 we see clinically. I have never gone in to a 12 patient -- you know, do surgery on a patient 13 and found a particle to be a source of pain 14 or causing problems at all. 15 MR. FAES: I'm going to object 16 and move to strike after the word 17 "potential." 18 BY MR. FAES: 19 Q. You go on to say on the same 20 page that, "Also, during the surgery, the 21 site can be irrigated and suctioned, which 22 would dispose of any particles." 23 Is that correct? 24 A. That's correct.</p>

8 (Pages 26 to 29)

Christina Pramudji, M.D.

Page 30	Page 32
<p>1 Q. Isn't it true that the site 2 can't be irrigated and suctioned if the 3 particle becomes loose after the surgery is 4 completed and the incision is closed? 5 A. That doesn't happen. 6 Q. That was not my question, 7 whether or not it happens. My question was, 8 isn't it true that the site can't be 9 irrigated and suctioned if a particle becomes 10 loose after the surgery is completed and the 11 incision is closed? 12 A. Yes, that is correct, to answer 13 that hypothetical question. 14 Q. You state on page 29 of your 15 report that, "The protective sheath over the 16 mesh bears the forces as the mesh is passed 17 through the pelvis and as noted the mesh is 18 placed tension free and spaced from the 19 urethra with an instrument like a dilator 20 before removing the sheaths." 21 Is that correct? 22 A. That's correct. 23 Q. So as you've stated here, 24 you've seen a surgeon before use a Babcock or</p>	<p>1 you don't believe that that causes any 2 clinical concerns to the patient if that 3 metal particle gets into the body because 4 it's in the packaging? 5 MR. GAGE: Object to form. 6 A. Okay. I'm picturing the 7 particles in the package that when you take 8 out the instruments and the implant, those 9 are not going to go into the patient. But 10 then you added in the part about it being 11 embedded in the mesh. So can you clarify 12 what you mean by that? 13 BY MR. FAES: 14 Q. Well, let me ask you this. If 15 there's a -- if there's metal particles loose 16 in the TVT mesh packaging, that could 17 potentially get imbedded in the mesh, 18 correct? 19 MR. GAGE: Object to form. 20 A. I can't envision that 21 happening. 22 BY MR. FAES: 23 Q. Let me ask you this. If a -- 24 if, hypothetically, a metal particle was</p>
Page 31	Page 33
<p>1 other instrument to hold the tape in place 2 while the sheaths are removed, correct? 3 A. Correct. 4 Q. Would you -- have you ever seen 5 a procedural video that was sent out to 6 physicians where the mesh appears to be being 7 stretched at that localized point where it's 8 being held in place by the Babcock while the 9 sheaths are being removed? 10 A. I can't recall as I sit here 11 right now. 12 Q. You also state, "Metal 13 particle" -- strike that. 14 You also state that, "Mesh 15 particles seen in packaging are also of no 16 clinical concern." 17 Is that correct? 18 A. That's correct. 19 Q. Is your opinion the same if 20 there are metal particles seen in packaging, 21 that those pose no clinical concern? 22 A. That's correct. 23 Q. So if there's metal particles 24 in the packaging or embedded within the mesh,</p>	<p>1 embedded in the mesh and the surgeon didn't 2 notice it and it got implanted into the 3 patient with metal particles in the mesh, 4 could that cause a clinical concern? 5 MR. GAGE: Object to form. 6 A. I really don't know, because we 7 do metal implants in orthopedic surgery. So 8 I -- I don't know the answer to that 9 question. 10 BY MR. FAES: 11 Q. Would you knowingly implant a 12 TVT product that it appeared that there were 13 foreign matter or metal within the mesh? 14 MR. GAGE: Object to form. 15 BY MR. FAES: 16 Q. Or would you go -- go to the 17 shelf and get out a different one that didn't 18 have that problem? 19 MR. GAGE: Object to form. 20 A. If I saw some metal in there, I 21 would probably go get another device or clean 22 it off or something. 23 BY MR. FAES: 24 Q. Do you know where the TVT and</p>

9 (Pages 30 to 33)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 34</p> <p>1 TVT-O are manufactured?</p> <p>2 A. No, I don't.</p> <p>3 Q. Well, I'll represent to you</p> <p>4 they're manufactured in Neuchâtel,</p> <p>5 Switzerland, which I'm sure the court</p> <p>6 reporter does not know how to spell.</p> <p>7 Were you aware that in 2010,</p> <p>8 the entire TVT-O and TVT production lines</p> <p>9 were shut down because there was an excess of</p> <p>10 foreign materials in the product in</p> <p>11 packaging?</p> <p>12 MR. GAGE: Object to form.</p> <p>13 A. No, I was not aware of that.</p> <p>14 BY MR. FAES:</p> <p>15 Q. Do you think that could</p> <p>16 potentially cause a clinical impact if there</p> <p>17 were foreign matter in the products in</p> <p>18 packaging of the TVT and TVT-O? Do you have</p> <p>19 any opinion on that?</p> <p>20 A. I don't really have an opinion</p> <p>21 on it.</p> <p>22 (Deposition Exhibit 20 marked.)</p> <p>23 BY MR. FAES:</p> <p>24 Q. Doctor, I'm going to hand you</p>	<p style="text-align: right;">Page 36</p> <p>1 the surgery and your relationship with</p> <p>2 Ethicon. Are you available to talk to me</p> <p>3 this week? I've also been trying to reach</p> <p>4 your colleague Dr. Melvyn Anhalt, though I</p> <p>5 haven't heard back yet."</p> <p>6 Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. And this e-mail gets forwarded</p> <p>9 to Burt Snell at Butler Snow; is that</p> <p>10 correct?</p> <p>11 A. Yes.</p> <p>12 Q. It's forwarded by you. And</p> <p>13 Burt Snell is a lawyer for Ethicon, who was</p> <p>14 actually here yesterday helping you prepare</p> <p>15 for your deposition; is that correct?</p> <p>16 A. That's correct.</p> <p>17 Q. First of all, do you recall if</p> <p>18 you ever replied to Amy Silverstein regarding</p> <p>19 this message?</p> <p>20 A. No, I did not.</p> <p>21 Q. Have you ever spoken to the</p> <p>22 press about mesh used for pelvic organ</p> <p>23 prolapse or stress urinary incontinence?</p> <p>24 A. Not that I can recall.</p>
<p style="text-align: right;">Page 35</p> <p>1 what's been marked as Exhibit 20 to your</p> <p>2 deposition, as soon as I get it out and get</p> <p>3 it marked.</p> <p>4 A. Is it material that this is not</p> <p>5 the updated CV? Does that matter?</p> <p>6 Q. Does it affect the answers to</p> <p>7 the questions I asked you?</p> <p>8 A. No.</p> <p>9 Q. No, then it doesn't.</p> <p>10 A. Okay.</p> <p>11 Q. Doctor, I've handed you what's</p> <p>12 been marked as Exhibit 20, and this is -- at</p> <p>13 least the first page of it is an e-mail dated</p> <p>14 April 21st, 2014, but the part of it that I</p> <p>15 want to focus is on the second page where the</p> <p>16 e-mail string begins, and it's an e-mail from</p> <p>17 an Amy Silverstein to you dated April 21st,</p> <p>18 2014. Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. It says, "Hi Dr. Pramudji: I'm</p> <p>21 a reporter with the Dallas Observer, working</p> <p>22 on a story about mesh used for transvaginal</p> <p>23 pelvic organ repair and incontinence surgery,</p> <p>24 and I've got a few questions for you about</p>	<p style="text-align: right;">Page 37</p> <p>1 Q. Do you recall any particular</p> <p>2 reason why you chose not to respond to this</p> <p>3 e-mail?</p> <p>4 A. No, I don't remember.</p> <p>5 Q. Do you know if Dr. Anhalt ever</p> <p>6 spoke with Ms. Silverstein or anyone else in</p> <p>7 the press?</p> <p>8 A. I don't know.</p> <p>9 Q. Now, this is dated April 21st,</p> <p>10 2014. Do you recall that this was about a</p> <p>11 month after the Batiste trial concluded?</p> <p>12 A. Yes.</p> <p>13 Q. And you know that Dr. Anhalt</p> <p>14 was -- testified in that case as an expert</p> <p>15 witness for Ethicon and Johnson & Johnson,</p> <p>16 correct?</p> <p>17 A. Yes, I was aware of that.</p> <p>18 Q. Do you still speak with</p> <p>19 Dr. Anhalt?</p> <p>20 A. Yes.</p> <p>21 Q. Do you speak with Dr. Anhalt</p> <p>22 about your consulting work with Ethicon and</p> <p>23 Johnson & Johnson?</p> <p>24 A. No, we have other things to</p>

10 (Pages 34 to 37)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 38</p> <p>1 talk about.</p> <p>2 Q. Have you ever spoken to the</p> <p>3 press about your relationship with Ethicon,</p> <p>4 as this reporter was requesting?</p> <p>5 A. I don't believe so.</p> <p>6 Q. Is that because you would</p> <p>7 prefer to keep the details about your</p> <p>8 relationship with Ethicon and Johnson &</p> <p>9 Johnson private?</p> <p>10 A. I don't have any reason to keep</p> <p>11 it private.</p> <p>12 Q. Doctor, I'm going to ask you</p> <p>13 about some adverse reactions and I'm going to</p> <p>14 ask if -- ask you whether or not you believe</p> <p>15 these are adverse events that can be</p> <p>16 associated with the TVT or TVT-O product.</p> <p>17 Okay?</p> <p>18 A. Okay.</p> <p>19 Q. Acute and/or chronic pain?</p> <p>20 A. Yes, as in other pelvic</p> <p>21 surgeries.</p> <p>22 MR. FAES: Object and move to</p> <p>23 strike after the answer "yes."</p> <p>24</p>	<p style="text-align: right;">Page 40</p> <p>1 BY MR. FAES:</p> <p>2 Q. Recurrence of incontinence?</p> <p>3 A. Yes, as in other incontinence</p> <p>4 surgeries.</p> <p>5 MR. FAES: Object and move to</p> <p>6 strike after the answer.</p> <p>7 BY MR. FAES:</p> <p>8 Q. Bleeding, including hemorrhage</p> <p>9 or hematoma?</p> <p>10 A. Yes, as in other surgeries.</p> <p>11 MR. FAES: Object and move to</p> <p>12 strike after the answer.</p> <p>13 BY MR. FAES:</p> <p>14 Q. One or more revision surgeries</p> <p>15 may be necessary to treat these adverse</p> <p>16 reactions?</p> <p>17 A. Yes, as in other pelvic</p> <p>18 surgeries.</p> <p>19 MR. FAES: Object and move to</p> <p>20 strike after the answer.</p> <p>21 BY MR. FAES:</p> <p>22 Q. Prolene mesh is a permanent</p> <p>23 implant that integrates into the tissue. In</p> <p>24 cases where the Prolene mesh needs to be</p>
<p style="text-align: right;">Page 39</p> <p>1 BY MR. FAES:</p> <p>2 Q. Voiding dysfunction?</p> <p>3 A. Yes, as in other pelvic</p> <p>4 surgeries.</p> <p>5 MR. FAES: Object and move to</p> <p>6 strike after the answer.</p> <p>7 BY MR. FAES:</p> <p>8 Q. Pain with intercourse which in</p> <p>9 some patients may not resolve?</p> <p>10 A. Yes, as in other pelvic</p> <p>11 surgeries.</p> <p>12 Q. I just have --</p> <p>13 MR. FAES: Object and move to</p> <p>14 strike after the answer.</p> <p>15 BY MR. FAES:</p> <p>16 Q. Neuromuscular problems,</p> <p>17 including acute and/or chronic pain in the</p> <p>18 groin, thigh, leg, pelvic and/or abdominal</p> <p>19 area may occur?</p> <p>20 A. Yes, as in other pelvic</p> <p>21 surgeries.</p> <p>22 MR. FAES: Object and move to</p> <p>23 strike after the answer.</p> <p>24</p>	<p style="text-align: right;">Page 41</p> <p>1 removed in part or whole, significant</p> <p>2 dissection may be required?</p> <p>3 A. Yes, as could occur with</p> <p>4 sutures in other pelvic surgeries.</p> <p>5 MR. FAES: Object and move to</p> <p>6 strike after the answer.</p> <p>7 BY MR. FAES:</p> <p>8 Q. Seroma?</p> <p>9 A. Yes, as in other pelvic</p> <p>10 surgeries.</p> <p>11 MR. FAES: Object and move to</p> <p>12 strike after the answer.</p> <p>13 BY MR. FAES:</p> <p>14 Q. Urge incontinence?</p> <p>15 A. Yes, as in other pelvic</p> <p>16 surgeries.</p> <p>17 MR. FAES: Object and move to</p> <p>18 strike after the answer.</p> <p>19 BY MR. FAES:</p> <p>20 Q. Urinary frequency?</p> <p>21 A. Yes, as in other pelvic</p> <p>22 surgeries.</p> <p>23 MR. FAES: Object and move to</p> <p>24 strike after the answer.</p>

11 (Pages 38 to 41)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 42</p> <p>1 BY MR. FAES:</p> <p>2 Q. Urinary retention?</p> <p>3 A. Yes, as in other pelvic</p> <p>4 surgeries.</p> <p>5 MR. FAES: Object and move to</p> <p>6 strike after the answer.</p> <p>7 BY MR. FAES:</p> <p>8 Q. Adhesion formation?</p> <p>9 A. Yes, as in other pelvic</p> <p>10 surgeries.</p> <p>11 MR. FAES: Object and move to</p> <p>12 strike after the answer.</p> <p>13 BY MR. FAES:</p> <p>14 Q. Atypical vaginal discharge?</p> <p>15 A. Yes, as in other pelvic</p> <p>16 surgeries.</p> <p>17 MR. FAES: Object and move to</p> <p>18 strike after the answer.</p> <p>19 BY MR. FAES:</p> <p>20 Q. Exposed mesh may cause pain or</p> <p>21 discomfort to the patient's partner during</p> <p>22 intercourse?</p> <p>23 A. Yes, as can occur with exposed</p> <p>24 sutures in other pelvic surgeries.</p>	<p style="text-align: right;">Page 44</p> <p>1 BY MR. FAES:</p> <p>2 Q. Yeah, I'll re-ask the question</p> <p>3 for the record to correct it. Doctor, are</p> <p>4 you aware of whether or not these are all</p> <p>5 adverse reactions that were added to the TVT</p> <p>6 and TVT-O IFU in May of 2015?</p> <p>7 A. Yes.</p> <p>8 Q. See, don't just agree with</p> <p>9 whatever I say.</p> <p>10 MR. GAGE: See, I was getting</p> <p>11 ready to -- I was going to do a</p> <p>12 speaking objection on that, if she had</p> <p>13 not clarified it.</p> <p>14 BY MR. FAES:</p> <p>15 Q. Doctor, do you know whether or</p> <p>16 not the list of adverse reactions that were</p> <p>17 added in May of 2015 are all risks that</p> <p>18 Ethicon knew about at the time the TVT was</p> <p>19 first launched in 2008?</p> <p>20 A. The TVT was first launched in</p> <p>21 2008?</p> <p>22 Q. 1998. Thank you.</p> <p>23 A. I'm not sure.</p> <p>24 Q. You just -- you don't know one</p>
<p style="text-align: right;">Page 43</p> <p>1 MR. FAES: Object and move to</p> <p>2 strike after the answer.</p> <p>3 BY MR. FAES:</p> <p>4 Q. Death?</p> <p>5 A. Yes, as in any surgery.</p> <p>6 MR. FAES: Object and move to</p> <p>7 strike after the answer.</p> <p>8 BY MR. FAES:</p> <p>9 Q. Doctor, are you aware of</p> <p>10 whether or not these are all adverse</p> <p>11 reactions that were added to the TVT and</p> <p>12 TVT-O IFU in May of 2014?</p> <p>13 MR. GAGE: Object to form.</p> <p>14 A. I believe that's correct.</p> <p>15 (Deposition Exhibit 21 marked.)</p> <p>16 BY MR. FAES:</p> <p>17 Q. I'll go ahead and mark a copy</p> <p>18 of that just so you're not flying blind,</p> <p>19 which is Exhibit 21.</p> <p>20 MR. FAES: You need one,</p> <p>21 William?</p> <p>22 THE WITNESS: Is it 2015? Is</p> <p>23 that what you meant to say?</p> <p>24</p>	<p style="text-align: right;">Page 45</p> <p>1 way or the other?</p> <p>2 A. No.</p> <p>3 Q. Are you aware that -- strike</p> <p>4 that.</p> <p>5 Do you know why Ethicon chose</p> <p>6 to add these adverse events to its IFU in</p> <p>7 2015?</p> <p>8 A. My understanding is that the</p> <p>9 Canadian board asked them to add some</p> <p>10 specific reactions, and they decided just to</p> <p>11 go ahead and put a long laundry list in</p> <p>12 there.</p> <p>13 Q. Do you believe that -- do you</p> <p>14 believe that these -- adding these -- strike</p> <p>15 that.</p> <p>16 Do you believe that Ethicon</p> <p>17 would've added all of these adverse reactions</p> <p>18 if they didn't believe they were necessary to</p> <p>19 support the continued sale of the device?</p> <p>20 MR. GAGE: Object to form.</p> <p>21 A. Could you repeat that for me?</p> <p>22 BY MR. FAES:</p> <p>23 Q. Sure. Do you believe that</p> <p>24 Ethicon would've added all these adverse</p>

12 (Pages 42 to 45)

Christina Pramudji, M.D.

Page 46	Page 48
<p>1 reactions if they didn't believe they were 2 necessary to support the continued sale of 3 the device? 4 MR. GAGE: Object to form. 5 A. I don't know. 6 BY MR. FAES: 7 Q. Are you aware that Dr. Martin 8 Weisberg was designated by Ethicon as a 9 corporate representative for why these IFU 10 changes were made? 11 A. Yes, I'm familiar with that. 12 Q. Have you read that deposition? 13 A. No, I haven't. 14 Q. Do you think that's a 15 deposition that would be important to you in 16 forming your opinions on this case? 17 A. No. 18 Q. You don't think it's important 19 to know why Ethicon chose to add these 20 adverse reactions to their IFU? 21 A. It doesn't change my opinions. 22 Q. Would you agree that this is a 23 significant IFU update? 24 A. They certainly added several</p>	<p>1 Q. Assuming that sales 2 representatives for Ethicon are not permitted 3 to discuss with doctors things that are not 4 contained within the IFU, would you agree 5 that this update would be helpful by allowing 6 sales representatives to discuss more 7 potential risks of the product with their 8 doctors? 9 A. Assuming that's true, then, 10 yes. 11 MR. FAES: I want to take just 12 a quick five-minute break, and it will 13 help me get organized and focused on 14 what I really need to do. 15 (Recess Taken From 11:54 a.m. 16 To 12:00 p.m.) 17 BY MR. FAES: 18 Q. Doctor, we're back on the 19 record after a short break. Are you ready to 20 proceed? 21 A. Yes. 22 Q. Doctor, you said that you 23 believe you spent ten hours preparing your 24 TVT and TVT-O report in this case?</p>
Page 47	Page 49
<p>1 things on there, which I think is reasonable, 2 but I don't think it's necessary. I think it 3 was adequate before they added all those in. 4 Q. Do you believe that these 5 additional adverse reactions that Ethicon 6 added to the IFU is helpful to pelvic 7 surgeons who may consider using the TVT? 8 A. Not particularly, since pelvic 9 surgeons are already familiar with all of 10 these adverse reactions. 11 Q. You don't believe that adding 12 this list of information to the IFU might 13 help physicians better consent their patients 14 for surgery with the TVT or TVT-O? 15 A. No. 16 Q. Would you agree that informed 17 consent is frequently guided by the contents 18 of an IFU for that particular device? 19 A. No, I don't think so. 20 Q. Do you know whether or not 21 Ethicon sales reps -- representatives are 22 allowed to discuss with their doctors things 23 that are not in the IFU? 24 A. I don't know about that.</p>	<p>1 A. Correct. 2 Q. Does that include all of the 3 time that you spent reviewing the expert 4 reports and materials cited by 5 Dr. Rosenzweig, Margolis and Carey? 6 A. Yes, since this was just an 7 update. 8 Q. So you believe it took you less 9 than ten hours to pull and look at every 10 footnote and document that they cited plus 11 update your report? 12 A. I believe so. I can't remember 13 specifically. 14 Q. Doctor, have you reviewed the 15 2015 deposition of Laura Angelini, because I 16 didn't see it on your reliance list? 17 A. I can't recall if I did or not. 18 Q. As someone who will be offering 19 opinions on whether the TVT mesh frays, 20 ropes, curls, unravels, loses particles or 21 deforms, wouldn't you want to have access to 22 a deposition of a TVT product director 23 discussing documents related to TVT, mesh 24 fraying, roping, losing particles, curling or</p>

13 (Pages 46 to 49)

Christina Pramudji, M.D.

Page 50	Page 52
<p>1 deforming?</p> <p>2 MR. GAGE: Object to form.</p> <p>3 A. I don't think it would change</p> <p>4 my opinions, so no.</p> <p>5 BY MR. FAES:</p> <p>6 Q. So you have no interest in</p> <p>7 seeing that?</p> <p>8 A. It would be interesting to see</p> <p>9 it.</p> <p>10 Q. But you'd agree that prior to</p> <p>11 issuing your report in this case, you did not</p> <p>12 review that deposition?</p> <p>13 A. I can't recall.</p> <p>14 Q. If you had reviewed that</p> <p>15 deposition, it would be on your reliance</p> <p>16 list, correct?</p> <p>17 A. Yes. But I may miss something</p> <p>18 here and there.</p> <p>19 Q. Do you know whether or not</p> <p>20 this -- the 2015 Laura Angelini deposition</p> <p>21 covered documents from the late 1990s and</p> <p>22 early 2000s that showed Ethicon was on notice</p> <p>23 that the mesh used in the TVT frayed, roped,</p> <p>24 curled, unraveled and lost particles?</p>	<p>1 be some things that I miss here and there</p> <p>2 unintentionally.</p> <p>3 Q. Do you know whether or not Tom</p> <p>4 Divilio was the product director when the TVT</p> <p>5 was launched?</p> <p>6 A. I don't know.</p> <p>7 Q. As someone who will be offering</p> <p>8 opinions on whether or not the TVT mesh</p> <p>9 frays, ropes, curls, unravels, loses</p> <p>10 particles and/or deforms, wouldn't you want</p> <p>11 to have access to a deposition where those</p> <p>12 things are being discussed by Ethicon's first</p> <p>13 medical director?</p> <p>14 A. No, not necessarily. I don't</p> <p>15 think it would change my opinions.</p> <p>16 Q. You don't think that the</p> <p>17 medical director at Ethicon who was there</p> <p>18 when the TVT was first launched in the United</p> <p>19 States can offer you any insight as to</p> <p>20 whether or not the TVT is defective?</p> <p>21 MR. GAGE: Object to form.</p> <p>22 A. I don't think that's going to</p> <p>23 trump my experience coupled with the</p> <p>24 literature.</p>
Page 51	Page 53
<p>1 MR. GAGE: Object to form.</p> <p>2 A. I don't recall.</p> <p>3 BY MR. FAES:</p> <p>4 Q. Do you know whether or not</p> <p>5 during that time frame, from 1998 to 2000,</p> <p>6 Ethicon initiated a mesh improvement product</p> <p>7 for the Prolene mesh but excluded the TVT</p> <p>8 mesh from that product -- from that project?</p> <p>9 Sorry.</p> <p>10 MR. GAGE: Object to form.</p> <p>11 A. I don't know about that.</p> <p>12 BY MR. FAES:</p> <p>13 Q. Have you reviewed the</p> <p>14 October 2014 deposition of Tom Divilio?</p> <p>15 A. Sounds vaguely familiar.</p> <p>16 Q. Do you know whether or not that</p> <p>17 deposition is on your reliance list?</p> <p>18 A. I don't remember. I would have</p> <p>19 to look.</p> <p>20 Q. If it's not on your reliance</p> <p>21 list, does that mean you haven't reviewed the</p> <p>22 deposition yet?</p> <p>23 A. Like I said, not -- you know, I</p> <p>24 try to get everything on there, but there may</p>	<p>1 BY MR. FAES:</p> <p>2 Q. Didn't ask whether it would</p> <p>3 trump your experience coupled with the</p> <p>4 literature. My question was, you don't think</p> <p>5 that the medical director at Ethicon who was</p> <p>6 there when the TVT was first launched in the</p> <p>7 United States can offer you any insight as to</p> <p>8 whether or not the TVT is defective?</p> <p>9 MR. GAGE: Object to form.</p> <p>10 A. That's correct.</p> <p>11 BY MR. FAES:</p> <p>12 Q. The testimony is -- of</p> <p>13 Ethicon's first medical director when TVT was</p> <p>14 launched isn't information that you would</p> <p>15 want to consider in informing your -- in</p> <p>16 forming your opinions in this case?</p> <p>17 A. I would consider it. I</p> <p>18 probably have looked at it, but it's not as</p> <p>19 important to me as the literature and my own</p> <p>20 experience, so no.</p> <p>21 Q. Are you going to offer an</p> <p>22 opinion in this case that the tensioning of</p> <p>23 the sling is the same whether or not the</p> <p>24 sling is made of mechanically cut mesh or</p>

14 (Pages 50 to 53)

Christina Pramudji, M.D.

Page 54	Page 56
<p>1 laser cut mesh?</p> <p>2 A. Yes, that's correct.</p> <p>3 Q. So if someone told you, for</p> <p>4 example, that a laser cut mesh needs to be</p> <p>5 tensioned more loosely under the urethra, you</p> <p>6 would disagree with that?</p> <p>7 A. Yes.</p> <p>8 Q. Do you know whether or not</p> <p>9 Ethicon's preceptors were telling doctors</p> <p>10 that with regard to the laser cut mesh</p> <p>11 products?</p> <p>12 A. I don't recall that.</p> <p>13 Q. But you were -- you were a</p> <p>14 preceptor -- in fact, you still are a</p> <p>15 preceptor for Ethicon, right?</p> <p>16 A. No, I haven't done any</p> <p>17 preceptoring for a few years.</p> <p>18 Q. Since 2013, right?</p> <p>19 A. Correct.</p> <p>20 Q. But you were a preceptor for</p> <p>21 Ethicon from 2004 to 2013, right?</p> <p>22 A. Correct.</p> <p>23 Q. And when you were preceptoring</p> <p>24 for Ethicon, you never told anyone that the</p>	<p>1 A. Maybe technically they call it</p> <p>2 a mini-sling. It has more length than the</p> <p>3 Abbrevio, so that's where I distinguish it.</p> <p>4 So I don't call it a mini-sling.</p> <p>5 Q. What has more length than the</p> <p>6 Abbrevio?</p> <p>7 A. I'm sorry, the Abbrevio has more</p> <p>8 length than the Secur.</p> <p>9 Q. Right. But you know that the</p> <p>10 Abbrevio is substantially shorter than the</p> <p>11 TVT-O product?</p> <p>12 A. Correct.</p> <p>13 Q. So I take it you would disagree</p> <p>14 with a physician if that physician said that</p> <p>15 he had to lay his laser cut mesh slings in</p> <p>16 much tighter than the mechanically cut ones</p> <p>17 in order to achieve success with the device?</p> <p>18 MR. GAGE: Object to form.</p> <p>19 A. Yes, I disagree.</p> <p>20 BY MR. FAES:</p> <p>21 Q. Would you agree that a</p> <p>22 responsible medical device company would</p> <p>23 determine the proper way to place a device</p> <p>24 before putting that product on the market?</p>
Page 55	Page 57
<p>1 laser cut mesh needs to be tensioned any</p> <p>2 differently than the mechanically cut mesh?</p> <p>3 A. Not that I can recall.</p> <p>4 Q. Did you --</p> <p>5 A. It's pretty much the same.</p> <p>6 Q. Did you ever tell anyone that</p> <p>7 the -- for example, the Abbrevio device needs</p> <p>8 to be tensioned differently than the TVT or</p> <p>9 TVT Exact?</p> <p>10 A. No.</p> <p>11 Q. Do you know whether or not, in</p> <p>12 fact, there are differences in the tensioning</p> <p>13 instructions between the TVT-O, the TVT Exact</p> <p>14 and the TVT Abbrevio?</p> <p>15 A. I can't recall, but</p> <p>16 practically, it's the same. The only one</p> <p>17 that was different was the mini-sling. But</p> <p>18 among the other ones, it's really pretty much</p> <p>19 the same tensioning.</p> <p>20 Q. And by "mini-sling," what do</p> <p>21 you mean? You mean the TVT-Secur?</p> <p>22 A. Correct.</p> <p>23 Q. Do you consider the TVT Abbrevio</p> <p>24 to be a mini-sling?</p>	<p>1 A. In surgery, there can be more</p> <p>2 than one proper way to do things. So I think</p> <p>3 it's responsible for the company to do their</p> <p>4 best to figure out a good way to do it, but</p> <p>5 there may be another way that evolves that's</p> <p>6 better.</p> <p>7 Q. So I'm not sure if I was clear</p> <p>8 on your answer. Do you agree or disagree</p> <p>9 that a responsible medical device company</p> <p>10 should determine the proper way to place a</p> <p>11 device before putting that product on the</p> <p>12 market?</p> <p>13 A. My answer would be yes, but</p> <p>14 recognizing that surgery is always evolving</p> <p>15 and things may change over time. So what may</p> <p>16 be proper at one time may not be proper later</p> <p>17 on, or there may be something more optimal,</p> <p>18 in other words.</p> <p>19 MR. FAES: Object and move to</p> <p>20 strike after the answer "yes."</p> <p>21 BY MR. FAES:</p> <p>22 Q. You were a preceptor for the</p> <p>23 TVT and Abbrevio at one time, correct?</p> <p>24 A. Yes.</p>

15 (Pages 54 to 57)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 58</p> <p>1 Q. And you instructed other 2 physicians on how to place that mesh? 3 A. Yes. 4 Q. Did anyone at Ethicon ever tell 5 you that the Abbrevo device should be placed 6 snugly so that the tissue pillows through the 7 mesh? 8 A. I don't recall that for 9 Abbrevo. 10 Q. Do you know if that -- whether 11 or not that was Ethicon's medical director's 12 opinion of how the tensioning technique for 13 the Abbrevo should be described? 14 A. I don't recall that. 15 Q. As someone who taught the 16 Abbrevo device to other surgeons, is that 17 information you would've wanted to know? 18 A. No, because I knew how to do 19 it, I knew how to get the results, so I 20 taught it the same way I taught the other 21 ones. 22 Q. Do you know that Ethicon 23 actually solicited feedback from surgeons 24 about the proper way to tension the TVT</p>	<p style="text-align: right;">Page 60</p> <p>1 A. Yes. 2 Q. Would you agree that the 3 properties of the mesh affect the safety 4 profile of the mesh? 5 A. Yes. 6 Q. Would you agree that the pore 7 size of the mesh is one property that affects 8 the safety profile of the mesh? 9 A. Yes. 10 Q. Would you agree that the 11 density of the mesh is one property that 12 affects the safety profile of the mesh? 13 A. Yes. I think the pore size and 14 density are important, and I think they got 15 it right. 16 Q. Do you agree that the weight of 17 the mesh is a property that affects the 18 safety profile of the mesh? 19 A. Yes. 20 Q. Do you agree that the 21 elasticity of the mesh is a property that 22 affects the safety of the mesh? 23 A. Well, in the sense the 24 elasticity can affect urinary retention if</p>
<p style="text-align: right;">Page 59</p> <p>1 Abbrevo device after it was launched? 2 A. I don't know about that. 3 Q. Did they ever ask for your 4 feedback on how to properly tension the 5 Abbrevo device? 6 A. I don't recall. 7 Q. Did they ever ask for your 8 feedback on how to properly tension any of 9 the TVT devices? 10 A. I don't recall. 11 Q. Would you have liked to have 12 been asked for your feedback on how to 13 properly tension the device since you seem 14 pretty sure about how to correctly do it? 15 MR. GAGE: Object to form. 16 A. Sure. 17 BY MR. FAES: 18 Q. Doctor, will you be offering 19 opinions in this case related to the 20 properties and performance of the TVT mesh? 21 A. Yes. 22 Q. Would you agree that the 23 properties of the mesh affect the performance 24 of the mesh?</p>	<p style="text-align: right;">Page 61</p> <p>1 it's too tight, so yes. 2 Q. Would you agree that stiffness 3 of the TVT mesh is one of the properties that 4 may affect the safety profile of the mesh? 5 A. Yes. It has to be flexible, 6 not too stiff, and that's what we see with 7 the TVT. 8 MR. FAES: Object and move to 9 strike after the word "stiff." 10 BY MR. FAES: 11 Q. Would you agree that the 12 surface area of the mesh is one property that 13 affects the safety profile of the mesh? 14 A. I don't know that that has much 15 bearing on the safety profile, so no. 16 Q. Do you agree that the tensile 17 strength of the TVT mesh is one property that 18 affects the safety profile of the mesh? 19 A. No, I think that speaks more to 20 the durability of the mesh. 21 Q. Well, would you agree that 22 tensile strength of the mesh is one property 23 that affects the efficacy of the mesh? 24 A. Yes.</p>

16 (Pages 58 to 61)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 62</p> <p>1 Q. Would you agree that surface</p> <p>2 area of the mesh is one property that affects</p> <p>3 the efficacy of the mesh?</p> <p>4 A. Yes, I can agree with that,</p> <p>5 because if it were really narrow or really</p> <p>6 wide, it could change the efficacy.</p> <p>7 Q. Would you agree that if the</p> <p>8 mesh were too narrow to the point of a</p> <p>9 string, it could affect the efficacy or cause</p> <p>10 urinary retention?</p> <p>11 A. Yes, if it were too tight.</p> <p>12 Q. Doctor, do you know what the</p> <p>13 standard is that a manufacturer should follow</p> <p>14 when designing mesh products?</p> <p>15 MR. GAGE: Object to form.</p> <p>16 A. Whose standard are you</p> <p>17 referring to?</p> <p>18 BY MR. FAES:</p> <p>19 Q. I'm just asking, do you know of</p> <p>20 any standards that manufacturers should or</p> <p>21 must follow in designing mesh products?</p> <p>22 A. Not that I'm aware of.</p> <p>23 Q. Are you familiar with ISO</p> <p>24 standards at all?</p>	<p style="text-align: right;">Page 64</p> <p>1 company researches -- a medical device</p> <p>2 company researches before a product is</p> <p>3 designed?</p> <p>4 MR. GAGE: Object to form.</p> <p>5 A. I have ideas and conjectures,</p> <p>6 but I don't know specifically what they --</p> <p>7 what they do.</p> <p>8 BY MR. FAES:</p> <p>9 Q. Would you agree that surgery</p> <p>10 rates for stress urinary incontinence have</p> <p>11 increased since the introduction of the TVT?</p> <p>12 A. That surgery rates have</p> <p>13 increased? I think so, yes.</p> <p>14 Q. Have your surgery rates</p> <p>15 increased following the adoption of the TVT?</p> <p>16 A. Well, it's hard to say with me</p> <p>17 because I came out of training right when it</p> <p>18 was released. So I've --</p> <p>19 Q. So you don't have --</p> <p>20 A. -- only really practiced in the</p> <p>21 era of TVT.</p> <p>22 Q. So you can't really answer that</p> <p>23 because you don't have a really good</p> <p>24 before-and-after picture?</p>
<p style="text-align: right;">Page 63</p> <p>1 A. Not that I can remember.</p> <p>2 Q. Do you know what</p> <p>3 responsibilities a manufacturer holds in</p> <p>4 designing mesh products?</p> <p>5 A. No.</p> <p>6 Q. Do you know what kinds of</p> <p>7 things a medical device company researches</p> <p>8 before a product is designed or released?</p> <p>9 A. Could you repeat that question?</p> <p>10 Q. Sure. Do you know what kinds</p> <p>11 of things a company researches before a</p> <p>12 product is designed or released?</p> <p>13 MR. GAGE: Object to form.</p> <p>14 A. Well, I think they research the</p> <p>15 safety and efficacy of the product before</p> <p>16 they release it. Did I answer that question?</p> <p>17 BY MR. FAES:</p> <p>18 Q. Let me change my question a</p> <p>19 little bit.</p> <p>20 A. Okay.</p> <p>21 Q. Obviously they can't research</p> <p>22 the safety and efficacy of a device before</p> <p>23 it's designed. So I'll change the question</p> <p>24 to, do you know what kinds of things a</p>	<p style="text-align: right;">Page 65</p> <p>1 A. Correct.</p> <p>2 Q. You can answer if you know. Do</p> <p>3 you know if Dr. Anhalt's surgery rates</p> <p>4 increased following the adoption of TVT?</p> <p>5 A. I don't -- I don't know.</p> <p>6 Q. Are synthetic mesh products</p> <p>7 designed to increase surgery rates?</p> <p>8 A. I don't know if that's why</p> <p>9 they're designed.</p> <p>10 Q. Would you agree -- strike that.</p> <p>11 Do you agree or disagree with</p> <p>12 the following statement: Some physicians</p> <p>13 feel that the current mesh materials in</p> <p>14 slings are too hard and patients can feel it;</p> <p>15 a softer mesh may be of benefit to patients?</p> <p>16 A. I disagree.</p> <p>17 MR. GAGE: Time.</p> <p>18 MR. FAES: Want to go off the</p> <p>19 record for a second? I think I'm</p> <p>20 done. I might have like three more</p> <p>21 questions, or I may be done.</p> <p>22 (Recess Taken From 12:19 p.m.</p> <p>23 To 12:20 p.m.)</p> <p>24</p>

17 (Pages 62 to 65)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 66</p> <p>1 BY MR. FAES:</p> <p>2 Q. Doctor, we're back on the</p> <p>3 record. Are you ready to proceed?</p> <p>4 A. Yes.</p> <p>5 Q. Doctor, do you know who Schlomo</p> <p>6 Raz is?</p> <p>7 A. Yes.</p> <p>8 Q. Would you agree that he's one</p> <p>9 of the most respected pelvic floor surgeons</p> <p>10 in the world?</p> <p>11 A. Yes.</p> <p>12 Q. Would you agree that he's an</p> <p>13 expert in treating mesh complications?</p> <p>14 A. Probably at this point, yes.</p> <p>15 Q. Would you agree that he has</p> <p>16 more experience and expertise in pelvic floor</p> <p>17 surgery than you do?</p> <p>18 A. He's definitely got more</p> <p>19 experience, yes.</p> <p>20 MR. FAES: No further</p> <p>21 questions.</p> <p>22 EXAMINATION</p> <p>23 BY MR. GAGE:</p> <p>24 Q. Dr. Pramudji, do you recall</p>	<p style="text-align: right;">Page 68</p> <p>1 FURTHER EXAMINATION</p> <p>2 BY MR. FAES:</p> <p>3 Q. Doctor, when you serve as an</p> <p>4 expert, you want to be fair and impartial,</p> <p>5 right?</p> <p>6 A. Correct.</p> <p>7 Q. In order to be fair and</p> <p>8 impartial, you want to review the evidence</p> <p>9 and get all sides of the story, right?</p> <p>10 A. Correct.</p> <p>11 MR. FAES: No further</p> <p>12 questions.</p> <p>13 MR. GAGE: So we're done.</p> <p>14 (Deposition Concluded At</p> <p>15 12:22 p.m.)</p> <p>16 --o0o--</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
<p style="text-align: right;">Page 67</p> <p>1 being asked about whether you had reviewed</p> <p>2 certain depositions of Ethicon employees?</p> <p>3 A. Yes.</p> <p>4 Q. And in response to one of those</p> <p>5 questions, you said, the fact whether you</p> <p>6 reviewed one or more of those depositions was</p> <p>7 not going to trump your experience and the</p> <p>8 literature. Do you recall that response?</p> <p>9 A. Yes.</p> <p>10 Q. What does that mean?</p> <p>11 A. That means that the body of</p> <p>12 literature and my own experience in over a</p> <p>13 thousand patients is more important to my</p> <p>14 opinions than the opinions of company</p> <p>15 employees.</p> <p>16 Q. Why is that?</p> <p>17 A. Because that is the actual</p> <p>18 clinical outcome, actually what is happening</p> <p>19 when you put in a TVT, and it's -- my</p> <p>20 experience and the data show that it is very</p> <p>21 safe and very efficacious.</p> <p>22 MR. GAGE: No more questions.</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 69</p> <p>1 CERTIFICATE</p> <p>2 I, MICHEAL A. JOHNSON, Registered</p> <p>3 Diplomate Reporter, Certified Realtime</p> <p>4 Reporter, Certified Court Reporter and Notary</p> <p>5 Public, do hereby certify that prior to the</p> <p>6 commencement of the examination, CHRISTINA</p> <p>7 PRAMUDJI, M.D. was duly sworn by me to</p> <p>8 testify to the truth, the whole truth and</p> <p>9 nothing but the truth.</p> <p>10 I DO FURTHER CERTIFY that the</p> <p>11 foregoing is a verbatim transcript of the</p> <p>12 testimony as taken stenographically by and</p> <p>13 before me at the time, place and on the date</p> <p>14 hereinbefore set forth, to the best of my</p> <p>15 ability.</p> <p>16 I DO FURTHER CERTIFY that pursuant</p> <p>17 to FRCP Rule 30, signature of the witness was</p> <p>18 not requested by the witness or other party</p> <p>19 before the conclusion of the deposition.</p> <p>20 I DO FURTHER CERTIFY that I am</p> <p>21 neither a relative nor employee nor attorney</p> <p>22 nor counsel of any of the parties to this</p> <p>23 action, and that I am neither a relative nor</p> <p>24 employee of such attorney or counsel, and</p> <p>that I am not financially interested in the</p> <p>action.</p> <p>18 MICHEAL A. JOHNSON, RDR, CRR</p> <p>19 NCRA Registered Diplomate Reporter</p> <p>20 NCRA Certified Realtime Reporter</p> <p>21 Certified Court Reporter</p> <p>22 Notary Public in and for the</p> <p>23 State of Texas</p> <p>24 My Commission Expires: 8/8/2016</p> <p>Dated: March 24, 2016</p>

18 (Pages 66 to 69)

Christina Pramudji, M.D.

<p style="text-align: right;">Page 70</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition over</p> <p>4 carefully and make any necessary corrections.</p> <p>5 You should state the reason in the</p> <p>6 appropriate space on the errata sheet for any</p> <p>7 corrections that are made.</p> <p>8 After doing so, please sign the</p> <p>9 errata sheet and date it.</p> <p>10 You are signing same subject to</p> <p>11 the changes you have noted on the errata</p> <p>12 sheet, which will be attached to your</p> <p>13 deposition.</p> <p>14 It is imperative that you return</p> <p>15 the original errata sheet to the deposing</p> <p>16 attorney within thirty (30) days of receipt</p> <p>17 of the deposition transcript by you. If you</p> <p>18 fail to do so, the deposition transcript may</p> <p>19 be deemed to be accurate and may be used in</p> <p>20 court.</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 72</p> <p>1 ACKNOWLEDGMENT OF DEPONENT</p> <p>2</p> <p>3</p> <p>4 I, CHRISTINA PRAMUDJI, M.D., do</p> <p>5 hereby certify that I have read the foregoing</p> <p>6 pages and that the same is a correct</p> <p>7 transcription of the answers given by me to</p> <p>8 the questions therein propounded, except for</p> <p>9 the corrections or changes in form or</p> <p>10 substance, if any, noted in the attached</p> <p>11 Errata Sheet.</p> <p>12</p> <p>13 CHRISTINA PRAMUDJI, M.D. DATE</p> <p>14</p> <p>15 Subscribed and sworn to before me this</p> <p>16 _____ day of _____, 20 ____.</p> <p>17 My commission expires: _____</p> <p>18</p> <p>19 _____</p> <p>20 Notary Public</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
<p style="text-align: right;">Page 71</p> <p>1 ERRATA</p> <p>2 PAGE LINE CHANGE</p> <p>3 _____</p> <p>4 REASON: _____</p> <p>5 _____</p> <p>6 REASON: _____</p> <p>7 _____</p> <p>8 REASON: _____</p> <p>9 _____</p> <p>10 REASON: _____</p> <p>11 _____</p> <p>12 REASON: _____</p> <p>13 _____</p> <p>14 REASON: _____</p> <p>15 _____</p> <p>16 REASON: _____</p> <p>17 _____</p> <p>18 REASON: _____</p> <p>19 _____</p> <p>20 REASON: _____</p> <p>21 _____</p> <p>22 REASON: _____</p> <p>23 _____</p> <p>24 REASON: _____</p>	<p style="text-align: right;">Page 73</p> <p>1 LAWYER'S NOTES</p> <p>2</p> <p>3 PAGE LINE</p> <p>4 _____</p> <p>5 _____</p> <p>6 _____</p> <p>7 _____</p> <p>8 _____</p> <p>9 _____</p> <p>10 _____</p> <p>11 _____</p> <p>12 _____</p> <p>13 _____</p> <p>14 _____</p> <p>15 _____</p> <p>16 _____</p> <p>17 _____</p> <p>18 _____</p> <p>19 _____</p> <p>20 _____</p> <p>21 _____</p> <p>22 _____</p> <p>23 _____</p> <p>24 _____</p>

19 (Pages 70 to 73)

Christina Pramudji, M.D.

Page 74

A	affect 14:14 35:6 59:23 60:3,24 61:4 62:9 agree 29:2 44:8 46:22 47:16 48:4 50:10 56:21 57:8 59:22 60:2,6 60:10,16,20 61:2,11,16,21 62:1,4,7 64:9 65:10,11 66:8 66:12,15 ahead 43:17 45:11 allen 4:8 allowed 47:22 allowing 48:5 amsden 2:11 4:10 amy 35:17 36:18 andrew 4:2 andy 8:7 angelini 49:15 50:20 anhalt 36:4 37:5 37:13,19,21 anhalts 65:3 answer 22:24 30:12 33:8 38:23 39:6,14 39:23 40:6,12 40:20 41:6,12 41:18,24 42:6 42:12,18 43:2 43:7 57:8,13 57:20 63:16 64:22 65:2 answers 35:6 72:5 anyway 27:16 apart 25:12,18 26:13 appearances 6:4 appeared 33:12 appears 31:6	appropriate 70:6 approximately 13:14,19 april 35:14,17 37:9 area 14:23 39:19 61:12 62:2 articles 10:8,11 10:13 asked 15:5 18:8 35:7 45:9 59:12 67:1 asking 62:19 associated 38:16 assuming 27:13 48:1,9 attached 70:12 72:7 attention 16:12 attorney 69:13 69:14 70:16 attorneys 14:4 atypical 42:14 autologous 18:20 19:4 available 23:14 23:24 36:2 avenue 4:3,13 aware 34:7,13 37:17 43:9 44:4 45:3 46:7 62:22	beforeandafter 64:24 beginning 3:9 begins 35:16 believe 11:2,17 12:17 16:6 17:3 28:14 32:1 38:5,14 43:14 45:13,14 45:16,18,23 46:1 47:4,11 48:23 49:8,12 bellew 12:8,9 benefit 65:15 best 10:14 57:4 69:8 better 47:13 57:6 bill 13:18 billed 13:9 biological 18:21 18:22,23 19:4 19:7 bit 63:19 bladder 18:5 26:19 27:7 bleeding 40:8 blind 43:18 blynn 1:23 board 45:9 body 32:3 67:11 boggs 2:5 boston 19:13,17 19:24 20:3 box 16:5 break 48:12,19 brenda 1:11 bridges 2:7 bulking 18:24 burt 36:9,13 business 16:23 butler 5:2 22:2 36:9 butlersnow 5:3	c 4:1,6 5:1 call 56:1,4 canadian 45:9 cant 20:8 22:9 23:2 26:6 30:2 30:8 31:10 32:20 49:12,17 50:13 55:15 63:21 64:22 carefully 70:4 carey 2:8 21:6 49:5 carol 2:23 carpenter 1:12 4:20 cartmell 4:2 case 1:7,8,10,11 1:13,14,16,17 1:19,20,22,23 2:1,3,4,6,7,9 2:10,12,13,15 2:16,18,19,21 2:22,24 8:9 11:12 12:7 26:8 37:14 46:16 48:24 50:11 53:16,22 59:19 cases 9:14 13:2 40:24 casespecific 13:4 13:15 cathy 2:10 cause 28:6,15,21 28:24 29:4 33:4 34:16 42:20 62:9 causes 32:1 causing 29:14 cerda 4:6,7 certain 67:2 certainly 46:24 certificate 6:11 69:1 certified 3:11 69:2,3,19,19
	B			
	babcock 30:24 31:8 back 9:17 36:5 48:18 66:2 baker 2:1 banks 1:18 barbara 1:8 based 13:21 batiste 37:11 bearing 61:15 bears 30:16	C		

Christina Pramudji, M.D.

Page 75

certify 69:3,6,10 69:12 72:4 change 24:22 26:11 46:21 50:3 52:15 57:15 62:6 63:18,23 71:2 changed 12:21 changes 46:10 70:11 72:6 charlene 2:20 charleston 1:2 choice 17:15 choose 17:24 chose 22:6 27:15 37:2 45:5 46:19 chosen 24:1 christina 1:10 3:5 6:1,6 7:1,4 7:5 8:2 69:4 72:4,12 chronic 38:19 39:17 circumstance 28:16 cite 10:11 cited 10:8 11:1 21:17,22 49:4 49:10 city 3:8 4:4 clarified 44:13 clarify 28:18 32:11 classic 15:17 clean 33:21 clear 57:7 clinical 16:19 24:23 31:16,21 32:2 33:4 34:16 67:18 clinically 16:14 28:1 29:11 closed 30:4,11 coaptite 18:23 cole 2:8	colleague 36:4 colony 5:3 com 4:3,7,12,18 5:3 commencement 69:4 commission 69:21 72:17 companies 20:10,14,18 company 56:22 57:3,9 63:7,11 64:1,2 67:14 compared 17:20 completed 30:4 30:10 completing 11:20 complications 14:23 66:13 component 25:9 concern 31:16 31:21 33:4 concerns 32:2 concluded 37:11 68:14 conclusion 69:11 conjectures 64:5 consent 47:13 47:17 consider 47:7 53:15,17 55:23 consultant 20:2 consulting 20:11 20:15,19 37:22 contacted 11:11 11:15 contain 9:22 contained 12:19 48:4 containing 9:20 contents 47:17 continue 8:22 continued 45:19 46:2	continuing 9:8,9 control 10:15 copy 14:11 43:17 corporate 46:9 correct 8:14 12:12,17 13:10 13:11,16,17,24 14:3,9,24 15:21,22 21:7 21:19 23:11,12 23:16,17,22 24:2 25:14,15 26:20,21 27:4 28:2,8 29:23 29:24 30:12,21 30:22 31:2,3 31:17,18,22 32:18 36:10,15 36:16 37:16 43:14 44:3 49:1 50:16 53:10 54:2,19 54:22 55:22 56:12 57:23 65:1 68:6,10 72:5 corrections 70:4 70:7 72:6 correctly 12:8 59:14 couldnt 28:6 counsel 4:5,10 4:15,20 5:5 69:13,14 couple 15:6 20:6 coupled 52:23 53:3 court 1:1 34:5 69:3,19 70:20 covered 50:21 create 12:4 crr 69:18 cumbersome 16:22 curled 50:24	curling 49:24 curls 49:20 52:9 current 65:13 currently 15:7,8 15:17 16:15 18:17 19:8,16 20:10,14,19 24:12 cut 15:24 16:1 16:10 53:24 54:1,4,10 55:1 55:2 56:15,16 cv 7:5 14:8,12 14:17,19 35:5 <hr/> D <hr/> d 1:10 3:6 6:1,6 7:1,4 8:2 69:4 72:4,12 dallas 4:9 35:21 damage 26:18 27:7 daphne 2:1 data 10:14 24:23 25:10,19,20 67:20 date 3:10 69:8 70:9 72:12 dated 35:13,17 37:9 69:22 day 72:16 days 70:16 de 4:6,7 death 43:4 decided 45:10 decisionmaking 10:10 deemed 70:19 defective 52:20 53:8 defendants 5:5 definitely 66:18 definitively 27:10 deforming 50:1 deforms 49:21	52:10 density 60:11,14 deponent 6:13 72:1 deposed 12:22 deposing 70:15 deposition 1:10 3:5 7:1 8:8 9:1 9:5,11 10:21 14:15 34:22 35:2 36:15 43:15 46:12,15 49:15,22 50:12 50:15,20 51:14 51:17,22 52:11 68:14 69:11 70:3,13,17,18 depositions 21:18 67:2,6 described 27:1 58:13 description 7:3 7:15 design 25:11 designated 46:8 designed 63:8 63:12,23 64:3 65:7,9 designing 62:14 62:21 63:4 details 24:3 38:7 determine 22:13 56:23 57:10 developed 24:10 device 16:16 17:19 20:14 24:2 33:21 45:19 46:3 47:18 55:7 56:17,22,23 57:9,11 58:5 58:16 59:1,5 59:13 63:7,22 64:1 devices 17:2 59:9
--	---	--	---	---

Christina Pramudji, M.D.

Page 76

didnt 33:1,17 45:18 46:1 49:16 53:2 difference 16:5 differences 55:12 different 33:17 55:17 differently 55:2 55:8 dilator 30:19 dimock 2:23 diplomat 3:11 69:2,18 directly 28:5,11 director 49:22 52:4,13,17 53:5,13 directors 58:11 disagree 13:6 54:6 56:13,19 57:8 65:11,16 discharge 42:14 discomfort 28:7 28:15,21 29:5 42:21 discuss 10:3 47:22 48:3,6 discussed 10:2 52:12 discussing 49:23 dispose 29:22 dissection 41:2 distinguish 56:3 district 1:1,1,8 divilio 51:14 52:4 division 1:2 doctor 8:7 9:3 12:24 14:8,17 15:7 34:24 35:11 38:12 43:9 44:3,15 48:18,22 49:14 59:18 62:12 66:2,5 68:3	doctors 47:22 48:3,8 54:9 document 21:22 49:10 documents 21:24 49:23 50:21 doesnt 8:17 16:14 30:5 35:9 46:21 doing 18:4 20:10 20:14,19 70:8 donna 2:11 dont 12:9 14:13 16:3,7,11,11 16:13 17:3 18:15 22:17,24 24:3,9 25:5 27:19,19 28:14 32:1 33:6,8 34:2,20 37:4,8 38:5,10 44:8 44:24 46:5,18 47:2,11,19,24 50:3 51:2,11 51:18 52:6,14 52:16,22 53:4 54:12 56:4 58:8,14 59:2,6 59:10 61:14 64:6,19,23 65:5,5,8 dr 9:11 35:20 36:4 37:5,13 37:19,21 46:7 49:5 65:3 66:24 drawing 10:5 drive 4:19 drs 21:6 duly 8:3 69:4 durability 61:20 durham 1:21 dysfunction 39:2 dyspareunia	26:17 27:7 <hr/> E <hr/> e 4:1,1 5:1,1 earlier 8:13 19:20 early 50:22 edwards 4:6 edwardsdelac... 4:7 effect 28:1 efficacious 67:21 efficacy 61:23 62:3,6,9 63:15 63:22 either 11:5 elasticity 60:21 60:24 elizabeth 1:23 email 7:7 35:13 35:16,16 36:8 37:3 embedded 31:24 32:11 33:1 employee 69:13 69:14 employees 67:2 67:15 employing 23:7 emptying 18:5 engineers 26:1,9 enrolling 16:18 entire 34:8 envision 32:20 equivalent 24:17 25:2 era 64:21 errata 6:12 70:6 70:9,11,15 71:1 72:7 esquire 4:2,7,12 4:17 5:2 essentially 23:20 essman 1:6 estimate 12:1	13:1,13 estimated 13:3 ethicon 1:3 18:8 23:14 24:1,10 24:15 26:1,9 27:15 36:2,13 37:15,22 38:3 38:8 44:18 45:5,16,24 46:8,19 47:5 47:21 48:2 50:22 51:6 52:17 53:5 54:15,21,24 58:4,22 67:2 ethicons 14:3 20:22 52:12 53:13 54:9 58:11 eugenia 2:4 events 38:15 45:6 evidence 68:8 evolves 57:5 evolving 57:14 exact 15:8,13,18 16:9 17:8,17 18:14,14 55:9 55:13 examination 6:6 8:5 66:22 68:1 69:4 example 54:4 55:7 excess 34:9 excluded 51:7 exhibit 7:4,5,7,8 7:16 8:22 9:1,4 9:8,9 10:20 11:6,7 14:15 34:22 35:1,12 43:15,19 exhibits 7:1,13 9:17 experience 52:23 53:3,20	66:16,19 67:7 67:12,20 expert 7:4 9:19 11:11,13,15 18:10 21:4,10 21:18 22:7 37:14 49:3 66:13 68:4 expertise 66:16 expires 69:21 72:17 exposed 42:20 42:23 <hr/> F <hr/> f 1:18 fact 54:14 55:12 67:5 facts 10:3,3 faes 4:2 6:7,9 8:6,7,21 9:2,15 9:21 10:17 14:16 22:16,23 24:20 25:6 26:7 27:21 29:1,15,18 32:13,22 33:10 33:15,23 34:14 34:23 38:22 39:1,5,7,13,15 39:22 40:1,5,7 40:11,13,19,21 41:5,7,11,13 41:17,19,23 42:1,5,7,11,13 42:17,19 43:1 43:3,6,8,16,20 44:1,14 45:22 46:6 48:11,17 50:5 51:3,12 53:1,11 56:20 57:19,21 59:17 61:8,10 62:18 63:17 64:8 65:18 66:1,20 68:2,11
---	--	---	---	---

Christina Pramudji, M.D.

Page 77

fail 70:18 fair 20:21 68:4,7 familiar 24:13 24:19 46:11 47:9 51:15 62:23 far 10:1,14 fascial 18:20 19:4 fashion 19:11 23:20 fda 24:15 25:2 february 12:16 feedback 58:23 59:4,8,12 feel 65:13,14 felt 10:4,13 figure 57:4 file 1:3 financially 69:15 fine 8:24 firm 4:17 first 8:3 11:11 11:14 26:20 35:13 36:17 44:19,20 52:12 52:18 53:6,13 fiveminute 48:12 flat 23:21 flexible 61:5 floor 19:23 23:5 26:24 66:9,16 flying 43:18 focus 35:15 focused 48:13 follow 62:13,21 following 26:19 26:22 64:15 65:4,12 follows 8:4 footnote 49:10 forces 30:16 foregoing 69:7 72:4	foreign 33:13 34:10,17 form 24:18 25:4 26:5 27:17 28:17 32:5,19 33:5,14,19 34:12 43:13 45:20 46:4 50:2 51:1,10 52:21 53:9 56:18 59:15 62:15 63:13 64:4 72:6 formation 42:8 forming 11:4 46:16 53:16 forth 69:8 forwarded 36:8 36:12 found 29:13 fox 1:20 frame 51:5 frayed 50:23 fraying 49:24 frays 49:19 52:9 frcp 69:10 free 30:18 frequency 41:20 frequently 47:17 friction 28:10,10 28:13,24 29:6 front 10:19 12:5 further 66:20 68:1,11 69:6 69:10,12 future 19:20	46:4 50:2 51:1 51:10 52:21 53:9 56:18 59:15 62:15 63:13 64:4 65:17 66:23 67:22 68:13 gather 22:2 general 11:20 13:19 gessner 3:8 getting 44:10 given 72:5 giving 27:1 go 29:19 32:9 33:16,16,21 43:17 45:11 65:18 going 8:21 9:3 9:16 14:13,14 15:16 29:15 32:9 34:24 38:12,13 44:11 52:22 53:21 67:7 good 57:4 64:23 goodwin 1:8 graft 18:23 grand 4:3 groin 39:18 guided 47:17 gynecare 7:8 gynemesh 9:13 13:20,22	65:14 havent 36:5 46:13 51:21 54:16 heard 36:5 heather 2:13 held 3:7 31:8 help 47:13 48:13 helped 22:2 helpful 47:6 48:5 helping 36:14 hematoma 40:9 hemorrhage 40:8 hereinbefore 69:8 heres 22:16 herman 4:11,11 hes 66:8,12,18 hhklawfirm 4:12 hi 35:20 highland 5:3 hill 1:8 hold 31:1 holds 63:3 hour 13:10 hours 11:19,24 12:2 13:1,3,5,9 13:21,23 48:23 49:9 houston 3:8,9 4:19 huskey 12:10,10 hypothetical 30:13 hypothetically 32:24	47:18,23 48:4 ill 8:18 14:11 27:11 34:3 43:17 44:2 63:23 im 8:8,21 9:3 14:14 18:4 24:13,19 25:21 27:18 29:15 32:6 34:5,24 35:20 38:12,13 44:23 46:11 56:7 57:7 62:19,22 65:19 imbedded 32:17 impact 34:16 impartial 68:4,8 imperative 70:14 implant 17:19 32:8 33:11 40:23 implanted 17:1 17:4,6 33:2 implants 33:7 important 10:5 12:20 46:15,18 53:19 60:14 67:13 improvement 51:6 incision 30:4,11 inclined 18:6 include 27:15 49:2 including 39:17 40:8 incontinence 18:3,18 20:23 23:8 35:23 36:23 40:2,3 41:14 64:10 increase 65:7 increased 19:5 64:11,13,15 65:4
	<hr/> G <hr/> gage 5:2,3 6:8 8:24 9:6 22:22 24:18 25:4 26:5 27:17 28:17 32:5,19 33:5,14,19 34:12 43:13 44:10 45:20	<hr/> H <hr/> hadnt 12:14 hagans 2:2 hand 9:3 34:24 handed 35:11 hands 17:16 happen 30:5 happening 32:21 67:18 happens 30:7 hard 64:16	<hr/> I <hr/> ideas 64:5 ifu 27:8,13,16 43:12 44:6 45:6 46:9,20 46:23 47:6,12	

index 6:1	johnson 3:10	L	look 25:22 49:9	mary 1:14
individuals 22:8	37:15,15,23,23	la 4:6,6	51:19	master 1:3
information	38:8,9 69:2,18	la 4:6,7	looked 53:18	material 10:22
47:12 53:14	joseph 1:8	laser 15:24	loose 29:3 30:3	19:12 24:16
58:17	joy 1:6	16:10 54:1,4	30:10 32:15	35:4
informed 47:16	judge 1:8	54:10 55:1	loosely 54:5	materially 14:13
informing 53:15	K	56:15	loses 49:20 52:9	materials 10:24
initiated 51:6	k 1:18	late 50:21	losing 25:13	11:3 21:17
insight 52:19	kansas 4:4	launched 44:19	26:13 49:24	27:2 34:10
53:7	katz 4:11	44:20 52:5,18	lost 50:24	49:4 65:13
instructed 58:1	keep 38:7,10	53:6,14 59:1	louisiana 4:14	math 13:6,17
instructions 7:9	key 2:19	laundry 45:11	loyal 20:22	14:2
55:13 70:1	kidney 19:24	laura 49:15	M	matter 16:14
instrument	kinds 63:6,10,24	50:20	m 1:10 3:6,9	33:13 34:17
30:19 31:1	kit 19:10	law 4:17	4:12 5:2 6:1,6	35:5
instruments	kits 23:7	lawyer 36:13	7:1,4 8:2 48:15	mdl 1:5
27:2 32:8	klein 7:5	lawyers 6:14	48:16 65:22,23	mean 22:16
integrates 40:23	knew 44:18	73:1	68:15 69:4	32:12 51:21
integrity 25:13	58:18,19	lay 56:15	72:4,12	55:21,21 67:10
26:14	know 8:18 11:13	leg 39:18	manipulator	meaning 11:12
intercourse	15:24 16:3,4,8	length 56:2,5,8	19:21	means 9:9 67:11
28:14 29:6	16:11,13 19:10	level 10:14	manufactured	meant 43:23
39:8 42:22	19:16 22:21	liability 1:4	34:1,4	mechanically
interest 50:6	23:4,13 24:3,5	liked 59:11	manufacturer	16:1 53:24
interested 69:15	24:9,14 25:5	line 71:2 73:3	25:1 62:13	55:2 56:16
interesting 50:8	25:16,24 27:6	lines 34:8	63:3	medical 20:13
introduction	28:13 29:12	list 10:19,22	manufacturers	52:13,17 53:5
64:11	33:6,8,24 34:6	11:7 14:18	62:20	53:13 56:22
irrigated 29:21	37:5,8,13	22:14,19 44:16	march 1:15 3:2	57:9 58:11
30:2,9	44:15,24 45:5	45:11 47:12	6:2 7:2 69:22	63:7 64:1
irritation 28:24	46:5,19 47:20	49:16 50:16	margolis 21:6	melvyn 36:4
29:8	47:24 50:19	51:17,21	49:5	memorial 3:8
isnt 30:1,8 53:14	51:4,11,16,23	listed 11:5 22:13	maria 2:4,17	mentioned
iso 62:23	52:3,6 54:8	22:18,19	marie 1:18	18:19 19:20
issue 29:9,10	55:11 56:9	literature 52:24	mark 43:17	mesh 16:10 20:9
issued 12:12	58:10,17,22	53:4,19 67:8	marked 7:3,13	23:10,13,21
14:5	59:2 61:14	67:12	9:1,4,10 10:20	24:11,11,24
issuing 50:11	62:12,19 63:2	litigation 1:4	11:6,7 14:15	25:1,11 26:2
ive 12:24 35:11	63:6,10,24	little 63:19	34:22 35:1,3	26:12 27:24
35:24 36:3	64:6 65:2,3,5,8	llc 4:11	35:12 43:15	28:19 30:16,16
64:18	66:5	llp 4:2,17 5:2	market 24:2	30:17 31:6,14
J	knowingly	localized 31:7	25:3 56:24	31:24 32:11,16
jane 1:14	33:11	logan 2:20	57:12	32:17 33:1,3
jean 2:23	kott 4:12	lois 1:21	marketed 19:10	33:13 35:22
jo 2:16	kriz 1:9	long 2:13 45:11	martin 46:7	36:22 40:22,24
		longer 15:16		42:20 49:19,23

Christina Pramudji, M.D.

Page 79

50:23 51:6,7,8 52:8 53:24 54:1,4,10 55:1 55:2 56:15 58:2,7 59:20 59:23,24 60:3 60:4,7,8,11,12 60:17,18,21,22 61:3,4,12,13 61:17,18,20,22 61:23 62:2,3,8 62:14,21 63:4 65:6,13,15 66:13 meshes 25:10 message 36:19 metal 31:12,20 31:23 32:3,15 32:24 33:3,7 33:13,20 micheal 3:10 69:2,18 midstream 16:21 midurethral 15:2 17:7 18:21 mikalia 4:12 miniarc 17:10 minisling 55:17 55:20,24 56:2 56:4 mississippi 5:4 missouri 4:4 mixed 23:7,8 mkott 4:12 modify 11:22 12:4 month 37:11 morning 9:12 morrow 2:22 move 23:3 29:16 38:22 39:5,13 39:22 40:5,11 40:19 41:5,11 41:17,23 42:5	42:11,17 43:1 43:6 57:19 61:8 moved 16:20 multiply 13:12 <hr/> N <hr/> n 4:1,2 5:1 name 8:7 nancy 2:16 narrow 62:5,8 ncra 69:18,19 necessarily 52:14 necessary 27:20 40:15 45:18 46:2 47:2 70:4 need 22:21 43:20 48:14 needs 40:24 54:4 55:1,7 neither 69:13,14 neuchâtel 34:4 neuromuscular 39:16 never 14:22 29:11 54:24 new 4:14 12:19 notary 3:12 69:3 69:20 72:20 noted 30:17 70:11 72:7 notes 6:14 73:1 notice 3:7 33:2 50:22 november 11:17 number 7:3,15 13:1 numbers 8:22 9:8,10 13:13 <hr/> O <hr/> ooo 68:16 oath 8:13 object 24:18 25:4 26:5	27:17 28:17 29:15 32:5,19 33:5,14,19 34:12 38:22 39:5,13,22 40:5,11,19 41:5,11,17,23 42:5,11,17 43:1,6,13 45:20 46:4 50:2 51:1,10 52:21 53:9 56:18 57:19 59:15 61:8 62:15 63:13 64:4 objection 44:12 observer 35:21 obturator 15:9 15:14 24:10 obvious 26:23 27:14 obviously 63:21 occult 18:3 occur 26:17 39:19 41:3 42:23 occurs 28:14 october 51:14 offer 18:9 52:19 53:7,21 offered 16:10 offering 49:18 52:7 59:18 oh 12:10 okay 8:20,23 12:11 18:8 22:24 32:6 35:10 38:17,18 63:20 okeefe 4:13 olsen 1:14 once 17:11 ones 22:20 55:18 56:16 58:21 opinion 24:22	26:11 27:15 28:4 31:19 34:19,20 53:22 58:12 opinions 9:20,23 10:5,24 11:5 12:15,19 13:15 18:9 46:16,21 49:19 50:4 52:8,15 53:16 59:19 67:14,14 optimal 57:17 oral 3:5 order 56:17 68:7 organ 26:18 27:7 35:23 36:22 organized 48:13 original 15:20 70:15 orleans 4:14 orthopedic 33:7 outcome 67:18 <hr/> P <hr/> p 4:1,1,6 5:1,1 48:16 65:22,23 68:15 pa 24:5,9,15 package 32:7 packaging 31:15 31:20,24 32:4 32:16 34:11,18 page 21:3 23:3 25:7 26:16,20 26:22 27:22 29:20 30:14 35:13,15 71:2 73:3 pages 72:5 paid 13:13 14:3 pain 26:17 27:6 28:6,15 29:5 29:13 38:19 39:8,17 42:20 parkway 5:3	part 21:23 32:10 35:14 41:1 partially 25:9 particle 28:5 29:3,9,13 30:3 30:9 31:13 32:3,24 particles 27:23 28:20 29:22 31:15,20,23 32:7,15 33:3 49:20,24 50:24 52:10 particular 11:12 11:15 22:4,6 37:1 47:18 particularly 29:5 47:8 parties 69:13 partner 42:21 party 69:11 passed 30:16 patient 28:7 29:12,12 32:2 32:9 33:3 patients 16:19 17:23,24 18:3 24:24 39:9 42:21 47:13 65:14,15 67:13 paula 1:9 pay 16:12 pelvic 1:3 19:23 23:5 26:23 35:23 36:22 38:20 39:3,10 39:18,20 40:17 41:4,9,15,21 42:3,9,15,24 47:6,8 66:9,16 pelvis 30:17 penny 2:14 percent 17:21 percentage 17:18 perforation
--	---	---	---	---

Christina Pramudji, M.D.

Page 80

26:19 27:8 perform 17:24 18:17 performance 59:20,23 performing 26:24 periurethral 18:23 permanent 40:22 permitted 48:2 peter 4:7,7 pharmaceutical 20:18 physician 23:18 56:14,14 physicians 31:6 47:13 58:2 65:12 pick 16:5 picture 64:24 picturing 32:6 piece 28:11 pillows 58:6 place 31:1,8 56:23 57:10 58:2 69:8 placed 30:18 58:5 plaintiff 4:10,20 plaintiffs 4:5,15 21:5 please 8:18 70:3 70:8 plus 49:10 point 31:7 62:8 66:14 polypropylene 15:3 17:7 20:24 poor 18:5 pore 60:6,13 pose 31:21 potential 29:9 29:17 48:7	potentially 19:18 26:11 32:17 34:16 potts 4:17 pottslaw 4:18 practically 55:16 practiced 64:20 practices 16:20 pramudji 1:10 3:6 6:1,6 7:1,4 7:6 8:2 35:20 66:24 69:4 72:4,12 pramudjis 9:11 preceptor 54:14 54:15,20 57:22 preceptoring 54:17,23 preceptors 54:9 preceptorships 15:10,12,14 preconfigured 23:15,24 prefer 38:7 prepare 36:14 preparing 48:23 press 36:22 37:7 38:3 pretty 20:22 55:5,18 59:14 previous 10:21 11:23 12:3,7 previously 7:13 10:20 prior 9:11 50:10 69:3 private 38:9,11 probably 17:21 33:21 53:18 66:14 problem 22:17 26:1,4,10 27:19 33:18 problems 29:14 39:16	procedural 31:5 procedure 18:1 19:1 procedures 18:16 proceed 48:20 66:3 proceedings 8:1 product 15:18 19:10,14,19 33:12 34:10 38:16 48:7 49:22 51:6,8 52:4 56:11,24 57:11 63:8,12 63:15 64:2 production 34:8 products 1:4 15:11 16:9 17:4 18:19 19:17 20:1,23 34:17 54:11 62:14,21 63:4 65:6 profile 60:4,8,12 60:18 61:4,13 61:15,18 project 51:8 prolapse 18:4 28:22 36:23 prolene 28:5,11 28:19 40:22,24 51:7 prolift 9:13 13:21,22 proper 56:23 57:2,10,16,16 58:24 properly 59:4,8 59:13 properties 59:20 59:23 60:3 61:3 property 60:7 60:11,17,21 61:12,17,22	62:2 propounded 72:6 prosimas 9:13 13:20,22 protective 30:15 provided 14:8 ps 9:13 13:20,22 public 3:12 69:3 69:20 72:20 publications 14:18,19 15:1 published 14:22 pull 49:9 pursuant 3:7 69:10 put 13:5 27:18 45:11 67:19 putting 56:24 57:11 pvdff 23:6,7 <hr/> Q question 8:17,19 30:6,7,13 33:9 44:2 53:4 63:9 63:16,18,23 questions 14:14 35:7,24 65:21 66:21 67:5,22 68:12 72:6 quick 48:12 quijano 2:4 <hr/> R r 1:8 4:1,17 5:1 randomized 10:14 rates 64:10,12 64:14 65:3,7 raz 66:6 rdr 69:18 reach 36:3 reached 9:23 reactions 38:13 40:16 43:11	44:5,16 45:10 45:17 46:1,20 47:5,10 read 46:12 70:3 72:4 ready 44:11 48:19 66:3 realize 15:5 really 16:7,11,12 17:16 29:9,10 33:6 34:20 48:14 55:18 62:5,5 64:20 64:22,23 realtime 3:12 69:2,19 reask 44:2 reason 13:6 22:5 22:6 23:23 37:2 38:10 70:5 71:4,6,8 71:10,12,14,16 71:18,20,22,24 reasonable 27:20 47:1 recall 12:18 20:8 21:9,14 23:1,2 26:6 31:10 36:17,24 37:1 37:10 49:17 50:13 51:2 54:12 55:3,15 58:8,14 59:6 59:10 66:24 67:8 receipt 70:16 recess 48:15 65:22 recognizing 57:14 record 9:7 44:3 48:19 65:19 66:3 recurrence 40:2 refer 9:16 referenced 7:15
--	--	--	---	--

Christina Pramudji, M.D.

Page 81

regard 54:10 regarding 8:9 9:23 21:12 36:18 registered 3:11 69:2,18 related 49:23 59:19 relates 24:24 relationship 20:5 36:1 38:3 38:8 relative 69:13 69:14 release 63:16 released 63:8,12 64:18 reliance 10:18 11:7 22:14,18 49:16 50:15 51:17,20 relied 10:23 11:4 remember 12:8 17:13 22:9,15 25:21,23 37:4 49:12 51:18 63:1 removal 25:12 25:18 26:3,13 removed 31:2,9 41:1 removing 30:20 repair 1:3 18:4 35:23 repairs 28:22 repeat 45:21 63:9 rephrase 8:18 replied 36:18 report 7:4 9:19 9:22 10:2,4,6,9 10:10,12 11:1 11:6,12,21,23 12:3,4,6,11,16 12:20 13:4,20	13:21,22,23 14:9,12 21:3 22:20 23:4 25:8 26:17 27:23 30:15 48:24 49:11 50:11 reporter 3:11,12 34:6 35:21 38:4 69:2,3,3 69:18,19,19 reports 14:5 21:4,10,17,22 22:7 49:4 represent 27:11 34:3 representative 46:9 representatives 47:21 48:2,6 reps 47:21 requested 69:11 requesting 38:4 required 41:2 research 63:14 63:21 researches 63:7 63:11 64:1,2 resolve 39:9 respected 66:9 respond 37:2 response 67:4,8 responsibilities 63:3 responsible 56:22 57:3,9 results 58:19 retention 42:2 60:24 62:10 retropubic 15:13,17,19 18:7,22 return 70:14 review 21:21 22:6 27:9 50:12 68:8	reviewed 10:23 11:4 21:4,10 21:17 22:9,10 22:12,21 49:14 50:14 51:13,21 67:1,6 reviewing 49:3 reviews 10:15 revision 40:14 rhynhart 2:14 ricks 4:17 riddell 1:11 ridgeland 5:4 right 9:15 11:8 12:13 13:8 14:23 16:10 17:15 19:14 20:16,20 21:14 22:22 23:2,21 26:6 28:23 31:11 54:15,18 54:21 56:9 60:15 64:17 68:5,9 rigorous 10:16 risks 26:23 27:12 44:17 48:7 road 3:8 robin 2:7 roped 50:23 ropes 49:20 52:9 roping 49:24 rosenzweig 21:6 49:5 rule 69:10 <hr/> S <hr/> s 1:8 4:1 5:1 sacrocolpopexy 19:22 safe 67:21 safety 60:3,8,12 60:18,22 61:4 61:13,15,18 63:15,22	sale 45:19 46:2 sales 47:21 48:1 48:6 sandra 1:17 saw 33:20 says 9:7 35:20 schlomo 66:5 scientific 19:13 19:17 20:1,3 second 35:15 65:19 secur 56:8 see 22:17 28:21 29:11 35:18 36:6 44:8,10 49:16 50:8 61:6 seeing 50:7 seen 30:24 31:4 31:15,20 sense 8:17 60:23 sent 31:5 seroma 41:8 serve 68:3 served 11:13 set 16:22 69:8 setting 16:21 sharon 1:12 2:5 sheath 25:12,12 25:17,18 26:3 26:12,13 30:15 sheaths 26:2 30:20 31:2,9 sheet 70:6,9,12 70:15 72:7 shelf 33:17 sherry 1:20 shes 22:21 shively 2:19 4:15 short 48:19 shorter 56:10 show 25:10 67:20 showed 50:22 shut 34:9	sides 68:9 sign 18:5 70:8 signature 69:10 signed 12:16 significant 28:1 41:1 46:23 signing 70:10 silverstein 35:17 36:18 37:6 single 21:21 sit 31:10 site 29:21 30:1,8 size 60:7,13 skin 28:6,12 sling 14:23 15:20,23 16:1 16:2 17:15 18:10 23:15,19 23:20,24 24:10 53:23,24 slings 15:3,7 17:7,20 18:6 18:21,22 19:4 19:5,7 20:24 56:15 65:14 smith 1:18 snell 36:9,13 snow 5:2 22:2 36:9 snugly 58:6 softer 65:15 solicited 58:23 solved 26:4,9 solyx 16:16,19 17:1 soon 35:2 sorry 51:9 56:7 sound 13:24 sounds 12:13 13:8,17 51:15 source 29:13 southern 1:1 space 70:6 spaced 30:18 speak 37:18,21 speakerphone
---	--	---	---	---

Christina Pramudji, M.D.

Page 82

4:8,13,18 speaking 44:12 speaks 61:19 specific 45:10 specifically 12:18 14:19 15:2 21:5 49:13 64:6 spell 34:6 spent 11:20 12:1 48:23 49:3 spoke 37:6 spoken 36:21 38:2 sricks 4:18 stable 19:6 stand 14:3 standard 62:13 62:16 standards 62:20 62:24 start 16:23 state 3:13 21:4 21:16 23:4,5 25:7 26:16 27:22 30:14 31:12,14 69:21 70:5 stated 24:15 30:23 statement 65:12 states 1:1 23:6 52:19 53:7 stenographica... 69:7 stephen 4:17 stick 25:17 26:12 sticking 26:2 sticks 25:11 stiff 61:6,9 stiffness 61:2 stone 2:17 stones 19:24 story 35:22 68:9 street 4:8	strength 61:17 61:22 stress 18:3,18 20:22 36:23 64:10 stretched 31:7 strike 17:5 29:16 31:13 38:23 39:6,14 39:23 40:6,12 40:20 41:6,12 41:18,24 42:6 42:12,18 43:2 43:7 45:3,14 57:20 61:9 65:10 string 7:7 35:16 62:9 subject 70:10 submitted 21:5 subscribed 72:15 substance 72:7 substantially 24:16 25:2 56:10 success 56:17 suctioned 29:21 30:2,9 sui 23:7 24:24 26:24 27:2 suite 4:3,8,19 5:4 superficial 28:20 29:4,7 support 45:19 46:2 sure 26:15 27:18 34:5 44:23 45:23 57:7 59:14,16 63:10 surface 28:23 61:12 62:1 surgeon 30:24 33:1 surgeons 23:5	26:24 47:7,9 58:16,23 66:9 surgeries 26:18 26:24 38:21 39:4,11,21 40:4,10,14,18 41:4,10,16,22 42:4,10,16,24 surgery 27:3 29:12,20 30:3 30:10 33:7 35:23 36:1 43:5 47:14 57:1,14 64:9 64:12,14 65:3 65:7 66:17 surgical 18:16 19:1 27:1 suture 28:19 sutures 28:22 41:4 42:24 switzerland 34:5 sworn 8:3,14 69:4 72:15 synthetic 65:6 system 1:3 7:9 <hr/> T <hr/> take 8:8 24:8 32:7 48:11 56:13 taken 3:6 48:15 65:22 69:7 talk 36:2 38:1 tape 7:9 31:1 taught 58:15,20 58:20 taylor 2:20 4:15 tear 25:17 26:13 tears 25:12 technically 56:1 technique 58:12 techniques 27:1 tell 8:14 9:5 11:10 16:4 55:6 58:4	telling 54:9 ten 12:2 13:23 48:23 49:9 tend 18:2 tensile 61:16,22 tension 30:18 58:24 59:4,8 59:13 tensioned 54:5 55:1,8 tensionfree 7:8 tensioning 53:22 55:12,19 58:12 teri 2:19 terms 10:9 20:23 testified 8:4 12:22 37:14 testify 69:5 testimony 53:12 69:7 texas 3:9,13 4:9 4:19 23:6 69:21 thank 44:22 thats 8:24 12:4 12:17 14:13,24 15:15 17:13 19:13,22 23:12 24:11 25:15 26:21 28:5,8 29:24 30:22 31:18,22 36:16 43:14 46:14 48:9 52:22 53:10 54:2 56:3 57:5 61:6 65:8 theres 19:9 22:19,20 28:10 28:13 31:23 32:15,15 theyre 28:20 34:4 65:9 thigh 39:18 thing 19:23 things 19:24	37:24 47:1,22 48:3 52:1,12 57:2,15 63:7 63:11,24 think 11:8 12:7 12:9 14:13 17:10 18:15 20:6 27:20 34:15 46:14,18 47:1,2,2,19 50:3 52:15,16 52:22 53:4 57:2 60:13,14 61:19 63:14 64:13 65:19 thirty 70:16 thought 15:15 thousand 67:13 three 15:11 17:2 17:9 18:19 21:1 22:7,18 22:19 65:20 thursday 3:2 tight 61:1 62:11 tighter 56:16 time 11:23 12:21 16:24 17:18,22 23:1 44:18 49:3 51:5 57:15,16,23 65:17 69:8 tina 2:22 tissue 40:23 58:6 told 13:2 25:1 54:3,24 tom 51:14 52:3 total 14:2 training 64:17 transcript 69:7 70:17,18 transcription 72:5 transvaginal 35:22 treat 23:7 40:15 treating 66:13
--	---	---	--	---

Christina Pramudji, M.D.

Page 83

treatment 18:17 trial 16:19,21 37:11 trials 10:15 tried 17:10 true 23:9 27:14 30:1,8 48:9 trump 52:23 53:3 67:7 truth 8:14 69:5 69:5,5 try 8:18 16:22 51:24 trying 22:15 25:21 36:3 tv 1:6 3:6 7:8 8:9 9:20,24 10:23 11:13 12:6,14 13:23 14:20 15:8,9,9 15:13,13,17,18 15:18 16:9,9 17:8,8,17 18:1 18:14 21:12 23:15 25:11 27:23 29:3 32:16 33:12,24 34:8,18 38:16 43:11 44:5,18 44:20 47:7,14 48:24 49:19,22 49:23 50:23 51:7 52:4,8,18 52:20 53:6,8 53:13 55:8,9 55:13,14,23 57:23 58:24 59:9,20 61:3,7 61:17 64:11,15 64:21 65:4 67:19 tv 1:6 3:6 8:9 9:24 10:24 11:14 12:15 13:19 14:20 15:23 17:8	18:1 23:16 24:5,9,12,15 24:17 25:3 34:1,8,18 38:16 43:12 44:6 47:14 48:24 55:13 56:11 tv 18:9 55:21 twice 17:11 two 20:8 types 17:23 <hr/> U u 1:8 ui 23:8 ultimately 26:3 ultrapro 23:9,13 23:19,21 24:1 24:11,16,23 25:1,8,17 26:2 26:12 underneath 28:12 understand 8:10 8:12 15:19 understanding 45:8 unintentionally 52:2 united 1:1 23:6 52:18 53:7 unraveled 50:24 unravels 49:20 52:9 update 46:23 48:5 49:7,11 updated 12:14 35:5 uphold 19:19 urethra 30:19 54:5 urge 41:14 urinary 18:18 20:23 23:8	36:23 41:20 42:2 60:24 62:10 64:10 use 7:9 15:7,8,17 15:18,23,24 18:2 19:3,8,22 19:23 23:6,19 24:23 30:24 usually 19:9,11 <hr/> V vagina 27:24 28:6,9,12,13 29:4 vaginal 7:8 19:21 42:14 vaguely 51:15 various 10:3 verbatim 69:7 version 15:21,24 16:1 video 31:5 virginia 1:1,15 voiding 39:2 vypro 23:9 25:8 <hr/> W wagstaff 4:2 want 23:18 35:15 48:11 49:21 52:10 53:15 65:18 68:4,8 wanted 58:17 warlick 2:10 warned 27:8 wasnt 11:23 waugh 4:19 wave 11:16 13:2 13:16 14:6 21:11 way 45:1 56:23 57:2,4,5,10 58:20,24 wcllp 4:3 weak 18:5	week 36:3 weight 60:16 weisberg 46:8 wendy 2:2 west 1:1 westin 3:7 whats 9:4 35:1 35:11 white 1:15 wide 62:6 william 5:2,3 22:17 43:21 williams 2:16 wilson 1:23 witness 37:15 43:22 69:10,11 70:1 wolfe 1:17 word 29:16 61:9 words 57:18 work 20:11,15 20:19 25:10 37:22 worked 13:2 26:1 working 35:21 world 66:10 wouldnt 49:21 52:10 wouldve 45:17 45:24 58:17 writing 10:10 <hr/> X xenform 19:11 19:12,18 <hr/> Y yeah 22:5 23:2 28:21 44:2 year 12:16 20:7 years 15:6 17:2 17:9 19:5 20:7 21:1 54:17 yesterday 9:12 36:14	youd 50:10 youll 13:18 youre 8:12,13 19:16 20:18 43:18 youve 9:23 10:18,22 11:13 11:20 13:1 14:5,8,22 15:5 20:22 21:4 22:12 30:23,24 <hr/> Z <hr/> 0 00 48:16 000 13:14,14,19 14:4,5 04 7:7 <hr/> 1 1 13:2,16 14:6 10 3:9 7:16 100 4:8,19 1020 5:3 11 3:9 48:15 12 48:16 65:22 65:23 68:15 12cv00276 2:10 12cv00277 1:7 12cv00335 1:17 12cv00368 2:6 12cv00376 2:21 12cv00378 2:22 12cv00379 2:19 12cv00401 2:24 12cv00470 1:14 12cv00483 2:9 12cv00511 2:16 12cv00547 1:11 12cv00554 1:13 12cv00651 2:7 12cv00652 2:18 12cv00760 1:22 12cv00783 2:3 12cv00799 2:4 12cv00806 1:8
--	--	--	---	--

Christina Pramudji, M.D.

Page 84

12cv00878 1:20	49:15 50:20	68 6:9		
12cv00899 2:1	2016 1:15 3:2	69 6:11		
12cv00938 1:10	6:2 7:2 69:21			
12cv00958 1:16	69:22	<hr/> 7 <hr/>		
12cv00960 2:12	21 7:7,8 26:16	7 21:3		
12cv01119 2:15	43:15,19	700 13:5		
12cv01275 2:13	214 4:9	7011100 4:4		
12cv01286 1:23	21st 35:14,17	70113 4:14		
12cv01318 1:19	37:9	71 6:12		
12md02327 1:3	22 68:15	713 4:20		
13 7:16 10:20	2327 1:5	72 6:13		
11:7	24 1:15 3:2 6:2	73 6:14		
14 7:5	7:2 69:22	75204 4:9		
1400 5:4	252 13:14	77007 4:19		
18 7:4 9:1,4 11:6	28 27:22	<hr/> 8 <hr/>		
23:3	288 14:4	8 6:7 69:21,21		
19 7:5 14:12,15	29 30:14	816 4:4		
25:7 65:22	<hr/> 3 <hr/>	820 4:13		
1990s 50:21	30 13:3 69:10	<hr/> 9 <hr/>		
1998 15:20	70:16	9 7:4		
44:22 51:5	300 4:3	945 3:8		
<hr/> 2 <hr/>	3031 4:8	9485711 5:5		
2 1:3,7,8,10,11	34 7:7	95 17:21		
1:13,14,16,17	350 4:19	9638881 4:20		
1:19,20,22,23	36 13:19			
2:1,3,4,6,7,9	39157 5:4			
2:10,12,13,15	<hr/> 4 <hr/>			
2:16,18,19,21	4 6:4			
2:22,24	420 13:5,14			
20 7:7 34:22	43 7:8			
35:1,12 65:23	456 14:5			
72:16	4740 4:3			
2000 51:5	<hr/> 5 <hr/>			
2000s 50:22	50 13:3,21			
2004 54:21	504 4:14			
2008 44:19,21	54 48:15			
2010 34:7	5505239 4:9			
2013 54:18,21	5814892 4:14			
2014 7:7 12:12	<hr/> 6 <hr/>			
12:15,22 35:14	600 13:10			
35:18 37:10	601 5:5			
43:12 51:14	64112 4:4			
2015 11:18	66 6:8			
27:12,16 43:22				
44:6,17 45:7				